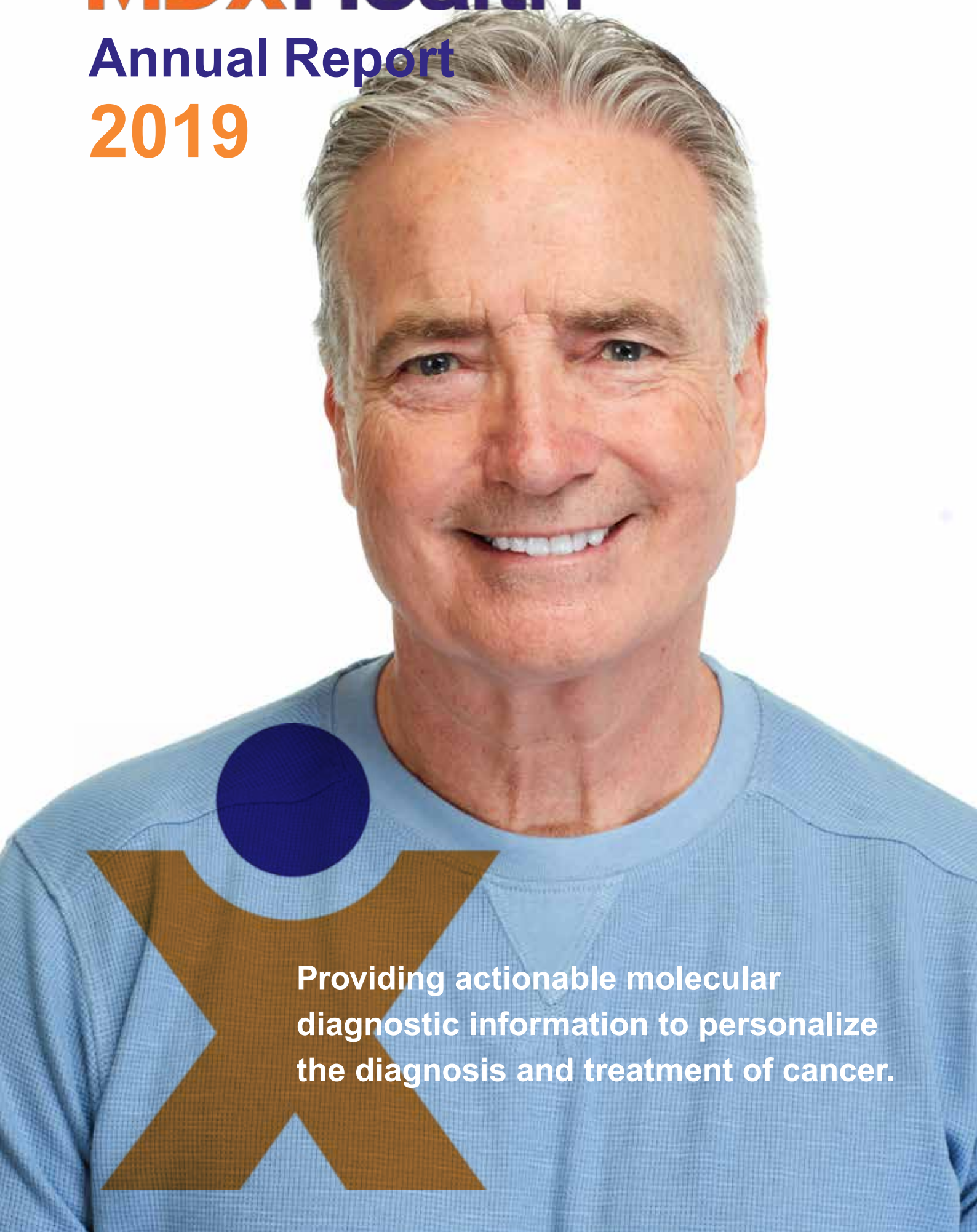


# MDxHealth<sup>®</sup>

## Annual Report

### 2019



Providing actionable molecular  
diagnostic information to personalize  
the diagnosis and treatment of cancer.

## About

**MDxHealth** is a multinational healthcare company that provides actionable molecular diagnostic information to personalize the diagnosis and treatment of cancer. Our tests are based on proprietary genomic, epigenetic and other molecular technologies and assist physicians with the diagnosis of urologic cancers, prognosis of recurrence risk, and prediction of response to a specific therapy.

**MDxHealth** continues to capitalize on the critical global trends in healthcare: the ever-growing need for early detection and, cost-effective solutions for diagnosing, monitoring and treating cancer. Our suite of commercial products addresses these unmet needs in a market which is currently estimated at \$4.2 billion and is expected to grow by 7% to \$4.6 billion in 2022.

MDxHealth's US headquarters and laboratory operations are based in Irvine, California.

MDxHealth's European headquarters are located in Herstal, Belgium, with laboratory operations in Nijmegen, The Netherlands. MDxHealth is listed on the Euronext Brussels stock exchange (Ticker symbol [MDXH.BR](#)).

### **Belgium Office**

CAP Business Center  
Rue d'Abhooz, 31  
4040 Herstal  
BELGIUM

### **US Offices and Laboratory**

15279 Alton Parkway  
Suite 100  
Irvine, CA 92618  
USA

### **EU Laboratory**

NovioTech Campus  
Transistorweg 5  
6534 AT Nijmegen  
THE NETHERLANDS

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# Message from the CEO

## Dear Shareholders,

At the time I write this letter to our valued shareholders, it is clear the global market and environment in which we operate, have changed dramatically since I joined MDxHealth last year. My first hope is that you are all well and endeavoring through this very difficult period. Before I get to the business of MDxHealth, I would like to take a moment to focus on our strongest asset – our people.

Throughout my career in the device and diagnostics space, I have worked with some of the highest quality people and best teams in the industry. However, the way the MDxHealth team has pulled together to address the challenges presented by the COVID-19 pandemic has been extraordinary. The result of this effort is to ensure that we are prepared to support our customers and their patients confidently and efficiently.

Just over a year ago, I made the decision to join the MDxHealth team. Despite the Company facing a number of challenges, it was clear that we offer a best-in-class menu of tests that aid in the diagnostic pathway of patients suspected of prostate cancer. What was also very clear, was that we needed to introduce two key and uncompromising commitments to focus and execution. While we have the potential to deliver clinical value in additional disease states, we are, and will be, a prostate cancer company.

As CEO, I feel it is important to underscore to you, our shareholders, what has changed at MDxHealth and in what ways the Company has moved forward in the last year. To that end, I can clearly and confidently state the following:

- Our team, strengthened by the addition of John Bellano as Chief Commercial Officer and Ron Kalfus as Chief Financial Officer, coupled with the leadership team in place when I joined, is now best-in-class;

- On the commercial side, we have led a transformation of our talent, focus and strategy based in our experience, data and metrics, validated and driven by the value of our customer base;
- We have restructured our revenue cycle management operation to drive improved cash collections and operating efficiency;
- We have a clinical value proposition and reimbursement coverage that provides a strong foundation for growth;
- We have visibility to Medicare coverage for our Select MDxHealth test; and,
- We have initiated and instituted an operating discipline across the organization that will drive and leverage capital allocation.

We remain confident in the potential of our unique products to provide urologists with a clear clinical pathway to accurately identify high-grade prostate cancer, while minimizing the use of invasive procedures. We believe this clinical pathway, with SelectMDx guiding cancer detection in a pre-biopsy setting and ConfirmMDx in a post-biopsy setting, will continue to drive momentum and market share.

I would like to close by thanking our shareholders and employees for your continued support and restating our unwavering commitment to deliver value to all our stakeholders including patients, customers, employees and shareholders.

Respectfully,

Belgium, April 28, 2020.

**Michael K. McGarrity**  
Chief Executive Officer



# Business Review



# Key Figures 2019

<p>Growth compared to FY 2018</p> <p>~41K patients tested</p> <p>+5%</p>	<p>\$11.8M total revenue</p> <p>2018: \$28.4m</p>	<p>\$43.2M operating loss</p> <p>2018: \$32.1m</p>	<p>\$-33.5M EBITDA</p> <p>2018: \$-29.1</p>	<p>\$22.1 Cash and cash equivalents</p>
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Thousands of \$ (except per share amounts) For the years ended December 31	2019	2018
Services	11,443	27,710
Licenses	250	512
Royalties	92	116
Government grants	0	59
<b>Revenues</b>	<b>11,785</b>	<b>28,397</b>
Cost of goods & services sold	-11,755	-11,652
<b>Gross profit</b>	<b>30</b>	<b>16,745</b>
Research and development expenses	-8,997	-4,280
General and administrative expenses	-15,196	-15,207
Selling and marketing expenses	-17,809	-29,591
Other operating income	1	261
Other operating expenses	-1,198	-26
<b>Operating Loss</b>	<b>-43,169</b>	<b>-32,098</b>
Financial income	10	21
Financial expenses	-516	-414
<b>Loss before income tax</b>	<b>-43,675</b>	<b>-32,491</b>
Income tax	575	41
<b>Loss for the year</b>	<b>-43,100</b>	<b>-32,450</b>
<b>Earnings per share attributable to parent (EPS)</b>		
Basic and Diluted, \$	-0.69	-0.56
<b>Number of shares</b>	<b>70,528,525</b>	<b>59,929,289</b>
<b>Consolidated statement of comprehensive income</b>		
Thousands of \$		
<b>Loss for the year</b>	<b>-43,100</b>	<b>-32,450</b>
<b>Other comprehensive income</b>		
<b>Items that will be reclassified to profit or loss:</b>		
Exchange differences arising from translation of foreign operations	253	-2,408
<b>Total comprehensive loss for the year (net of tax)</b>	<b>-42,847</b>	<b>34,858</b>

# Share Facts 2019

Stock exchange

Euronext: [MDXH.BR](#)

Total shares outstanding

70,528,525

52 week range

€ 0.86 - € 2.12

Market cap (as of Dec 31, 2019)

€ 73.3 million

Analyst coverage

US: - Taglich Brothers

EU: - Kempen

- KBC

- Degroof Petercam

Following the capital increase that was completed on 1 October 2019 by means of a private placement through an accelerated book building procedure, the share capital increased from € 47,813,068.45 to € 56,250,102.01 and the number of issued and outstanding shares increased from 59,939,289 to 70,528,525 ordinary shares, through the issuance of a total of 10,589,236 new shares.

MDxHealth has assembled a world-class team and acquired unique experience in the application of Next-Generation and Deep Sequencing technologies for the identification and validation of life-changing biomarkers.

MDxHealth is leveraging artificial intelligence (AI) for the development of novel genomic signatures which can improve the company's ability to detect cancer earlier, while there is the best opportunity for cure, and to help determine the most appropriate treatment regimen for an individual cancer patient.

MDxHealth has also partnered with leading academic institutions and other industry leaders to develop and validate diagnostic, prognostic and predictive tests to provide the least invasive approach to addressing a specific cancer type. Through these external collaborations, internal development efforts, in-licensing and acquisition, we have built a robust pipeline of biomarkers.

# Business Highlights 2019

## Overview 2019

### 2019 Business Review

2019 was a transformational year for MDxHealth, focused on assessing business and operating execution with the goal of demonstrating evidence of the turnaround required to deliver results that are sustainable and will build value for all stakeholders. With a continuing focus on our menu of ConfirmMDx and SelectMDx commercial tests, supported by the progress made in 2019 to refocus, restructure and deliver sustainable results, the Company is positioned to strengthen its leadership position in the detection of prostate cancer.

### Business Highlights

#### ConfirmMDx

- For the year ended December 31, 2019, billable test volume was down 5% to 18,195 versus 19,194 for 2018.

#### SelectMDx

- Positive draft Local Coverage Determination (LCD) for SelectMDx was released on August 22, 2019, which will provide coverage for qualified Medicare patients throughout the United States.
- For the year ended December 31, 2019, global billable test volume was up 61% to 21,669 versus 13,447 for 2018.

#### Business

- Strengthened management team with the appointments of Michael K. McGarrity as Chief Executive Officer, John Bellano as Chief Commercial Officer and Ron Kalfus as Chief Financial Officer.
- Timothy Still appointed as a Non-Executive Director of the Company in November 2019.

#### Partnerships

- In May 2019, MDxHealth entered into an agreement with a global diagnostics company to commence a joint development program for SelectMDx on its decentralized point-of-care system, with business and commercial terms to be further determined.
- In February 2019, MDxHealth signed an exclusive partnership agreement with LifeLabs to make SelectMDx® available in Canada.

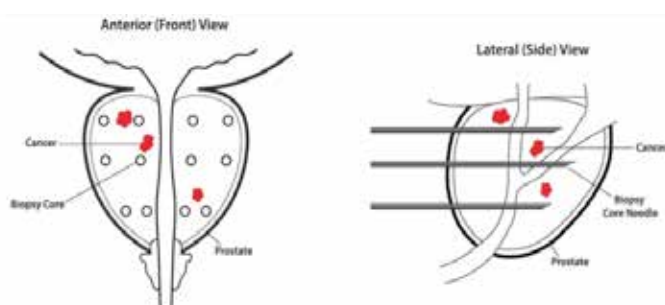
#### Clinical

- Positive data for SelectMDx and ConfirmMDx were presented at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU), California, February 14-16 2019. These presented data demonstrated:
  - o Annual cost savings of nearly \$500 million when SelectMDx is used prior to multiparametric magnetic resonance imaging (mpMRI) for the identification of US patients at high risk of aggressive prostate cancer;
  - o SelectMDx outperforms the Prostate Health Index (Phi) blood test for the detection of clinically significant prostate cancer prior to prostate biopsy;
  - o A retrospective validation of SelectMDx in German patients confirms robust clinical performance;
  - o Clinical utility study demonstrates that ConfirmMDx had a significant positive impact on repeat prostate biopsy decision-making.
- Data showing SelectMDx for Prostate Cancer urine test outperforms the Prostate Health Index (phi) blood test were presented at the 29th Annual International Prostate Cancer Update (IPCU) meeting in Beaver Creek, Co, January 24-27, 2019.



## Diagnostic Solutions

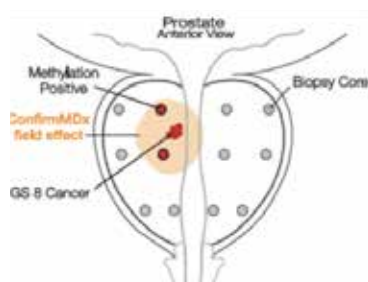
MDxHealth currently offers two complementary commercial stage solutions, ConfirmMDx for Prostate Cancer and SelectMDx for Prostate Cancer, which provide urologists with a clear clinical pathway to accurately identify clinically significant prostate cancer whilst minimizing the use of invasive procedures. ConfirmMDx and SelectMDx are designed to improve the early detection of clinically significant prostate cancer, but more importantly, to reduce the unnecessary costs associated with the diagnosis and treatment of prostate cancer.



## The ConfirmMDx for Prostate Cancer epigenetic assay

Unfortunately, ~30% of men with a cancer-negative prostate biopsy actually have cancer. Prostate cancer is difficult to diagnosis because it is both heterogenous and multi-focal. The gold standard for diagnosing prostate cancer is a transrectal ultrasound guided biopsy. This procedures samples less than 1% of the entire gland leaving men at risk for undetected prostate cancer.

ConfirmMDx is able to detect an epigenetic field effect associated with the presence of cancer at the DNA level. These DNA methylation changes are indistinguishable by histopathology. The test is able to help urologists determine a man's risk for harboring clinically significant prostate cancer despite having a cancer-negative biopsy result.



ConfirmMDx is covered by Medicare and has been included in the National Comprehensive Cancer Network Prostate Cancer Early Detection guidelines and the European Association of Urology Prostate Cancer

guidelines. There are over 55 studies on the genes and technology of ConfirmMDx.

## The SelectMDx for Prostate Cancer liquid biopsy assay

The current standard for prostate cancer screening is the Prostate Specific Antigen (PSA) blood test. Unfortunately, PSA is not specific to clinically significant prostate cancer – it is more of an indicator of prostate health. There are many factors such as BPH, inflammation, prostatitis and a naturally occurring enlarged prostate that can cause an elevated PSA. In men with an elevated PSA level between 3-10 ng/mL, only 25-40% of biopsies reveal cancer – and the majority of these identified cancers are indolent. Also, following a prostate biopsy procedure, ~18% of men suffer complications (blood in urine) and ~3% are hospitalized for infection (sepsis).

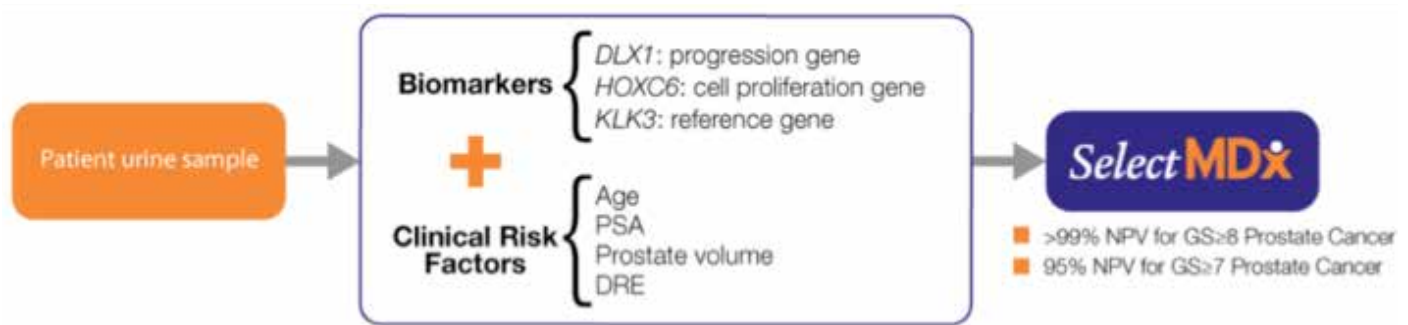
SelectMDx is an mRNA assay that helps physicians identify men at risk for clinically significant prostate cancer that may benefit from a prostate biopsy. SelectMDx measures the mRNA levels of 2 genes specific to clinically significant prostate cancer (HOXC6 and DLX1). The results of the genes are then combined with standard clinical risk factors in an advanced clinical model to determine a patient's risk for clinically significant cancer.

## Private placement

In October 2019, the Company raised US\$10.0 million (€9.0 million) in gross proceeds by means of a private placement of 10,589,236 new shares at an issue price of € 0.85 per share.

## Post period events

In December 2019, a novel strain of coronavirus causing COVID-19 was reported to have surfaced in Wuhan, China and has since spread to other parts of the world. On March 11, 2020, the World Health Organization declared the outbreak a pandemic. The COVID-19 pandemic is affecting the United States and global economies and may affect the Company's operations and those of third parties on which the Company relies. However, the impact on the business is unknown at this time. State and local authorities in the United States, Europe, and other countries, have since forced many businesses to temporarily shut down in an attempt to slow the spread of the virus, and citizens around the world are being told by public officials to stay at home and practice "social distancing". Global stock markets have reacted negatively, and many economists are projecting an economic slowdown, at least in the near term,



even if governments take emergency relief measures. Regardless of the extent of any economic slowdown, the outbreak could impact the Company's ability to develop business, conduct operations, and obtain components used in its business. The situation is constantly evolving, however, so the extent to which the COVID-19 outbreak will impact business and the economy is highly uncertain and is extremely difficult to predict. Accordingly, the Company cannot accurately predict the extent to which its 2020 financial condition and results of operations will be affected, however, management expects the impact to be limited and not to affect the Company's ability to continue as a going concern.

On April 20, 2020, the Company announced that its U.S. subsidiary, MDxHealth Inc., has entered into a "Paycheck Protection Program" (PPP) loan with the U.S. Small Business Administration (SBA) in the amount of \$2.3 million as part of the U.S. Coronavirus Aid, Relief, and Economic Security (CARES) Act. The loan has a term of two years and carries an interest rate of 1.0% per year. Payments on the loan are deferred for the first six months following disbursement of the loan, with principal and interest payments beginning on the seventh month. Interest on the loan continues to accrue during the six-month deferment period.

On April 24, 2020, the Company entered into a subscription agreement with MVM V LP and MVM GP (No.5) LP (collectively "MVM") pursuant to which MVM agreed to provide an equity investment to the Company for an aggregate amount of EUR 12.7 million (or approximately \$14 million). The equity investment will consist of a subscription of 20,162,924 new ordinary shares of the Company at an issue price of EUR 0.632 per share, representing a 5% discount to the 45-day volume weighted average price. The transaction is subject to limited customary conditions precedent, and is expected to close on or about 15 May 2020.

## 2020 outlook

The Company remains confident in the potential of its two complementary commercial stage products to provide urologists with a clear clinical pathway to accurately identify clinically significant prostate cancer, while minimizing the use of invasive procedures. The Company believes this clinical pathway, with SelectMDx guiding cancer detection in a pre-biopsy setting and ConfirmMDx in a post-biopsy setting, will continue driving momentum and increase market share on all fronts.

As a result of the COVID-19 global pandemic, the Company has suspended its 2020 guidance previously provided on February 26, 2020 as part of its 2019 year-end press release. Current market conditions and rapid developments on the COVID-19 front make it extremely difficult to project future results. The Company has taken necessary measures to ensure continued ability to provide its services to patients and physicians while keeping its employees safe.



## Part II:

# Corporate Governance

This section summarizes the main rules and principles of MDxHealth's Corporate Governance Charter. The complete Corporate Governance Charter is available on the MDxHealth website, at

<http://www.mdxhealth.com/shareholder-information>

## Introduction

This Corporate Governance Statement is included in the Company's report of the Board of Directors on the statutory accounts for the financial year ended on December 31, 2019 in accordance with Article 3:6, §2 of the Belgian Companies and Associations Code.

On May 17, 2019, the Belgian Royal Decree of May 12, 2019 designating the corporate governance code to be complied with by listed companies was published in the Belgian Official Gazette. On the basis of this royal decree, Belgian listed companies are required to designate the new 2020 Belgian Corporate Governance Code (the "2020 Code") as reference code within the meaning of Article 3:6, §2 of the Belgian Companies and Associations Code of March 23, 2019 (as amended) (the "Belgian Companies and Associations Code"). The 2020 Code applies compulsorily to reporting years beginning on or after January 1, 2020 (compulsory application). However, companies could already choose to apply the 2020 Code for reporting years beginning on or after January 1, 2019 (optional application).

The Company decided not to apply the 2020 Code prior to January 1, 2020 and therefore still applied during the financial year ended on December 31, 2019 the Belgian Code on Corporate Governance of March 12, 2009 (the "2009 Code").

The corporate governance charter that the Company applied in 2019 was adopted in accordance with the recommendations set out in the 2009 Code. For the financial year ended on December 31, 2019, the Company complied to a large extent with the provisions of the 2009 Code, except for the following deviations which the Company believed were justified in view of the Company's specific situation. Notably, in line with the "comply-or-explain" principle of said 2009 Code, MDxHealth did not fully comply with the following provisions:

- Given the size of the Company, no internal audit function existed in 2019.
- Before the entry into force of the Belgian Companies and Associations Code on January 1, 2020, share options were granted to Non-Executive Directors (including to Independent Directors). This was contrary to provision 7.7 of the 2009 Code, which provide that Non-Executive Directors should not be entitled to performance-related remuneration such as, amongst others, share-related long-term incentive schemes. The Company believed that these provisions of the 2009 Code were not appropriate and adapted to take into account the realities of companies in the biotech and life sciences industry that are still in a development phase. Notably, the ability to remunerate Non-Executive Directors with share options allowed the Company to limit the portion of remuneration in cash that the Company would otherwise need to pay to attract or retain renowned experts with the most relevant skills, knowledge and expertise. The Company was of the opinion that granting Non-Executive Directors the opportunity to be remunerated in part in share-based incentives rather than all in cash enabled the Non-Executive Directors to link their effective remuneration to the performance of the Company and to strengthen the alignment of their interests with the interests of the Company's shareholders. The Company believed that this was in the interest of the Company and its stakeholders. Furthermore, the Company believed that this was customary for Directors active in companies in the life sciences industry. In any event, as from the financial year started on January 1, 2020, the Company will no longer grant share options to Independent Directors.

The performance and functioning of the Board of Directors, its committees, and the Executive Management team are summarized below.

In the course of April 2020, the Board of Directors intends to approve an amended and restated version of the Company's corporate governance charter to align it with the provisions of the 2020 Belgian Code on Corporate Governance and the Belgian Companies and Associations Code. The Company intends to comply to a large extent with the provisions of the 2020 Code, except for the following deviations which the Company believes to be justified in view of the Company's specific situation. Notably, in line with the "comply-or-explain" principle of the 2020 Code, MDxHealth will not fully comply with the following provisions:

- Given the size of the Company, does not intend to put in place internal audit function. In line with provision 4.14, the need for an internal audit function will be reviewed annually.
- In accordance with provision 7.6 of the 2020 Code, the Non-Executive Directors should receive a part of their remuneration in the form of shares of the Company. As the Company currently does not hold any of its own shares as treasury stock, and does not have the ability to acquire its own shares, it cannot comply with this provision. Furthermore, the Board will propose to remunerate the Independent Directors in cash, but leaving it at the own initiative of the Independent Directors whether or not they wish to use such funds (in whole or in part) to acquire existing shares of the Company.
- In accordance with provision 7.9 of the 2020 Code, the Board should set a minimum threshold of shares to be held by the executive management. A part of the remuneration of the executive management consists of options to subscribe for the Company's shares, which should allow the executive management over time to acquire shares of the Company, in line with the objectives of the option plans.



- In accordance with provision 7.11 of the 2020 Code, stock options for executive management members should not vest and not be exercisable within less than three years. The Company's general shareholders' meeting approved in the past that share options can vest earlier than during three years, in line with what the Company believed to be customary for companies in the biotech and life sciences industry, including, notably, for management teams located in the U.S.

The articles of association and the corporate governance charter will be available on the Company's website (<https://mdxhealth.com/>) and can be obtained free of charge at the Company's registered office.

The 2020 Code and the 2009 Code can be accessed on the following website:

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# Board of Directors

The Company has opted for a “one tier” governance structure whereby the Board of Directors is the ultimate decision making body, with the overall responsibility for the management and control of the Company, and is authorized to carry out all actions that are considered necessary or useful to achieve the Company’s object. The Board of Directors has all powers except for those reserved to the general shareholders’ meeting by law or the Company’s articles of association. The Board of Directors acts as a collegiate body.

The Board of Directors’ role is to pursue sustainable value creation by the Company, by determining the Company’s strategy, putting in place effective, responsible and ethical leadership, and monitoring the Company’s performance. The Board of Directors acts as a collegiate body. Pursuant to the Belgian Companies and Associations Code and the articles of association of the Company, the Board of Directors should be composed of at least three Directors. In accordance with the 2009 Code and the 2020 Code, the Board of Directors should have a composition appropriate to the company’s purpose, its operations, phase of development, structure of ownership and other specifics. The Board of Directors shall be composed of at least three Independent Directors and a majority of the Board shall consist of Non-Executive Directors. Currently, the Board of Directors comprises 7 Directors, of which 4 are Non-Executive Independent Directors and 2 are Non-Executive Directors. The Directors of the Company are appointed by the general shareholders’ meeting.

The Company’s Board of Directors strives to maintain a well-balanced general diversity at the Board of Directors. Currently, there are 2 female Directors among a total of 7 Board members (representing a ratio of 28.6% female Directors against 71.4% male Directors). The Belgian Companies and Associations Code provides that at least one third of the members of the Board of Directors should be of the opposite gender. In order to calculate the required number of directors of a different gender, fractions must be rounded to the nearest whole number, which means that the Company’s board in its current composition must include at least 2 female Directors. The Company has met the one-third gender diversity requirement since January 1, 2018 and continues to comply with such requirement at the date of this Annual Report.

The Board of Directors is a collegial body, and deliberates and makes decisions as such. Excluding the Board committees meetings, the Board of Directors met 10 times throughout 2019. All Directors were present or represented at these 10 meetings, except that each of the following missed a single meeting during this period: Valiance Advisors LLP, represented by its permanent representative, Mr. Jan Pensaert; Qaly-Co BV, represented by its permanent representative, Dr. Lieve Verplancke; and Lab Dx L.L.C., represented by its permanent representative, Mr. Walter Narajowski.

## Chairman

The chairman of the Board of Directors is responsible for the leadership of the Board of Directors. The chairman takes the necessary measures to develop a climate of trust within the Board of Directors, contributing to open discussion, constructive dissent and support for the decisions of the Board of Directors. The chairman promotes effective interaction between the Board and the executive management. The chairman establishes a close relationship with the CEO, providing support and advice, while fully respecting the executive responsibilities of the CEO.

The Board of Directors appoints a chairman amongst the Non-Executive Directors. Currently, Ahok BV, with Mr. Koen Hoffman as permanent representative, is the chairman of the Board of Directors. Mr. Hoffman assumed the role of Board chair in 2019.

## Independent Directors

The Company has currently four Independent (Non-Executive) Directors.

A Director in a listed company is considered to be independent if he or she does not have a relationship with that company or with a major shareholder of the Company that compromises his or her independence. If the Director is a legal entity, his or her independence must be assessed on the basis of both the legal entity and his or her permanent representative. A Director will be presumed to qualify as an Independent Director if he or she meets at least the criteria set out in Article 7:87 of the Belgian Companies and Associations Code and Clause 3.5 of the 2020 Corporate Governance Code, which can be summarized as follows:

1. Not being an executive, or exercising a function as a person entrusted with the daily management of the company or an affiliated company or person, and not have been in such a position for the previous three years before their appointment. Alternatively, no longer enjoying share options of the company related to this position.
2. Not having served for a total term of more than twelve years as a Non-Executive Board member.
3. Not being an employee of the senior management (as defined in article 19,2° of the law of September 20, 1948 regarding the organization of the business industry) of the company or an affiliated company or person, and not have been in such a position for the previous three years before their appointment. Alternatively, no longer enjoying share options of the company related to this position.
4. Not receiving, or having received during their mandate or for a period of three years prior to their appointment, any significant remuneration or any other significant advantage of a patrimonial nature from the company or an affiliated company or person, apart from any fee they receive or have received as a Non-Executive Board member.
5. Not holding shares, either directly or indirectly, either alone or in concert, representing globally one tenth or more of the company's capital or one tenth or more of the voting rights in the company at the moment of appointment.
6. Not having been nominated, in any circumstances, by a shareholder fulfilling the conditions covered under point 5.
7. Not having, nor having had in the past year before their appointment, a significant business relationship with the company or an affiliated company or person, either directly or as partner, shareholder, board member, member of the senior management (as defined in article 19,2° of the law of September 20, 1948 regarding the organization of the business industry) of a company or person who maintains such a relationship.
8. Not being or having been within the last three years before their appointment, a partner or member of the audit team of the company or person who is, or has been within the last three years before their appointment, the external auditor of the company or an affiliated company or person.
9. Not being an executive of another company in which an executive of the company is a Non-Executive Board member, and not have other significant links with executive board members of the company through involvement in other companies or bodies.
10. Not having, in the company or an affiliated company or person, a spouse, legal partner or close family member to the second degree, exercising a function as board member or executive or person entrusted with the daily management or employee of the senior management (as defined in article 19,2° of the law of September 20, 1948 regarding the organization of the business industry), or falling in one of the other cases referred to in 1. to 9 above, and as far as point 2 is concerned, up to three years after the date on which the relevant relative has terminated their last term.

If the Board of Directors submits the nomination of an Independent Director who does not meet the abovementioned criteria to the general meeting, it shall explain the reasons why it assumes that the candidate is in fact independent.

The Company is of the view that the Independent Directors comply with each of the criteria of the Belgian Companies and Associations Code and the 2020 Code. The aforementioned Directors also complied with the criteria for being an Independent Director in 2019 pursuant to the former Belgian Companies Code of May 7, 1999 and the 2009 Code.

An Independent Director who ceases to satisfy the requirements of independence must immediately inform the chairman of the Board of Directors thereof.

## Composition of the Board of Directors

The table below describes the composition of the Board of Directors as of the date of this Annual Report.

Name	Age on Dec 31, 2019	Position	Term Start	Term End (1(2))	Professional Address
Ahok BV, represented by <b>Mr. Koen Hoffman</b>	51	Chairman, Non-Executive Independent Director	2018	2021	Absoluut Plaza Schoonzichtstraat 23A, B-9051 Gent, Belgium
<b>Mr. Michael K. McGarrity</b>	56	Executive Director	2019	2023	15279 Alton Parkway Ste 100 Irvine, CA 92618 USA
Gengest BV, represented by <b>Mr. Rudi Mariën</b>	74	Non-Executive Director	2017	2021	Karel van de Woestijnestraat 1-3, B-9000 Gent, Belgium
TSTILL Enterprises LLC, represented by <b>Mr. Timothy Still</b>	54	Non-Executive Independent Director	2019	2020	CAP Business Center, Rue d'Abhooz 31, B-4040 Herstal, Belgium
Valiance Advisors LLP, represented by <b>Mr. Jan Pensaert</b>	48	Non-Executive Director	2018	2021	Lilly House, 13 Hanover Square, London W1S 1HN, United Kingdom
Qaly-Co BV, represented by <b>Dr. Lieve Verplancke</b>	60	Non-Executive Independent Director	2017	2021	Dikkemeerweg 54, B-1653 Dworp, Belgium
Hilde Windels BV, represented by <b>Ms. Hilde Windels</b>	54	Non-Executive Independent Director	2017	2020	Kasteellaan 89, B-9000 Gent, Belgium

Notes:

- (1) The term of the mandates of each Director will expire immediately after the annual general shareholders' meeting held on the last Thursday of the month of May in the calendar year indicated.
- (2) In 2019, Mr. Walter Narajowski, as permanent representative of LabDx L.L.C., was Non-Executive Independent Director (until his resignation effective as of October 30, 2019). In addition, Dr. Jan Groen was Executive Director (until his resignation effective as of February 18, 2019).





**Mr. Koen Hoffman** obtained a Master in Applied Economics and an MBA at Vlerick Business School. Between 1992 and July 2016, he was active at KBC Group in which he started his career in the corporate finance department and later became the CEO of KBC Securities as from October 2012. Since August 2016, he is the CEO of Value Square asset management. Mr Koen Hoffman serves also as board member at Fagron (Chairman), Greenyard (chairman) Mithra Pharmaceuticals and SnowWorld.



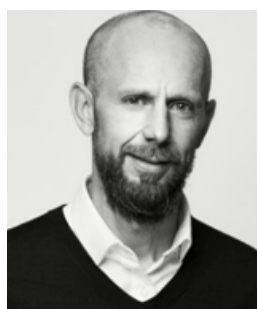
**Mr. Michael K. McGarrity** has more than 25 years of experience in the healthcare industry with a unique combination of device, diagnostics and biotechnology experience. Michael was most recently the CEO of Sterilis Medical. Prior to Sterilis Michael was the CEO of Nanosphere (NASDAQ: NSPH), a nanotechnology-based molecular diagnostics company, where he engineered an operational and strategic turnaround that resulted in its successful sale to Luminex (NASDAQ: LMNX) in 2016. Prior to Nanosphere, McGarrity spent 13 years at Stryker Corporation (NYSE: SYK).



**Mr. Rudi Mariën** is President and Managing Director of Gengest BV and Biovest NV. He was the Vice President of Cerba European Lab. Through his management company, Gengest BV, Mr. Mariën has Board mandates in different listed and private biotech companies. Mr. Mariën was co-founder, reference shareholder and Chairman of Innogenetics, and has been the founder, shareholder and Managing Director of several clinical reference laboratories including the Barc Group, a leading international centralized clinical laboratory, exclusively dedicated to pharmaceutical studies. Mr. Mariën holds a degree in pharmaceutical sciences from the University of Gent and is specialized in clinical biology.



**Mr. Timothy Still** has over 29 years of experience in medical devices and diagnostics. He has extensive experience in designing and implementing highly focused commercial and business development strategies within both large and small companies. Mr. Still has been directly responsible for building the commercial viability at many of his previous companies, five of which have been successfully acquired (representing >\$1.1B in proceeds). Mr. Still was most recently the President and CEO of Myoscience, located in Fremont, CA. Mr. Still was hired to develop a new commercial strategy at the company, and re-direct the technology platform into the pain management/orthopedic marketplace. While leading Myoscience, he raised over \$12M in convertible debt, rebuilt the commercial organization, and successfully negotiated a strategic exit in the Spring of 2019. Myoscience was acquired by Pacira Pharmaceuticals for a valuation of ~40X trailing revenue in an industry known for valuation ranges of ~7X. Mr. Still received a B.S. degree (with Honors) in Biological Sciences from the University of California at Davis, and an MBA (Deans Scholar) in Marketing and Entrepreneurship from the University of Southern California.



**Mr. Jan Pensaert** is the Founding Managing Partner of Valiance. He brings over 20 years of experience in growth investing. He leads the Investment Committee for the Valiance Funds and is responsible for all aspects of the Funds' investment processes. Jan currently serves on the Board of several Valiance entities funds and portfolio companies including MDxHealth, JenaValve, MyCartis and 4Tech. Prior to founding Valiance, Jan was CEO of La Fayette, where during his tenure the La Fayette Funds increased in AUM from \$750 million to \$5.5 billion. Before that, he was responsible for the Permal Group's European-based investment management and research activities, and prior to that he worked at Lazard in Corporate Finance M&A. Jan holds a BA in Business Economics from Gent University in Belgium, and a Masters in Banking & Finance from the University of Aix-Marseille, France.



**Lieve Verplancke MD**, a Belgian national, began her career in 1984 with The Beecham Group (now part of GlaxoSmithKline), and has since held key management positions with Merck & Co., as well as Bristol-Myers Squibb, where she served as Managing Director, leading their Belgian/GDL subsidiary, until 2012. Ms. Verplancke also serves as a Board Member for Brussels-based Europe Hospitals; the Imelda Hospital in Bonheiden; and the Euronext fund, Quest for Growth and Materialise. She is also the Founder and Managing Director of Qaly@Beersel, an elderly care center in Belgium. In addition to being a medical doctor (MD– KULeuven University), Ms. Verplancke holds a postgraduate degree in Economics and an MBA from the University of Antwerp. She has also completed courses at INSEAD, CEDEP, Columbia University and the Vlerick Business School, and is a certified Executive Coach (PCC).



**Hilde Windels** is the CEO of immunodiagnostic company Antelope Dx BV and has 20 years of experience in the biotechnology sector with a track record of building and structuring organizations, fundraising, M&A, public capital markets and corporate strategies. At Biocartis, she was CEO ad interim and Deputy CEO from September 2015 until September 2017 and CFO from 2011 until September 2015. Previously, Mrs. Windels worked as independent CFO for several private biotech companies and from 1999 to 2008 she was CFO of Devgen. Currently, Mrs. Windels serves as a board member at Erytech and Celyad. In the past, she also served on the boards of Devgen, Biocartis, Ablynx, VIB and FlandersBio. Mrs. Windels holds a Masters in Economics (commercial engineer) from the University of Leuven, Belgium.

## Committees of the Board of Directors

The Board of Directors of MDxHealth has set up two permanent board committees which are responsible for assisting the Board of Directors and making recommendations in specific fields: the audit committee (in accordance with Article 7:99 of the Belgian Companies and Associations Code, provision 5.2 of the 2009 Code and provision 4.10 of the 2020 Code) and the nomination and remuneration committee (in accordance with Article 7:100 of the Belgian Companies and Associations Code, provision 5.3 and 5.4 of the 2009 Code and provision 4.17 and 4.19 of the 2020 Code). The terms of reference of these board committees are primarily set out in the corporate governance charter.

### Audit Committee

MDxHealth has had an audit committee in place since the Company's inception. According to Article 7:99 §3 of the Belgian Companies and Associations Code, MDxHealth would meet the size criteria in order to operate without a separate audit committee, but the Company has chosen to continue operating with a separate audit committee.

The audit committee of the Company consists of three Directors. According to the Belgian Companies and Associations Code, all members of the audit committee must be Non-Executive Directors, and at least one member must be independent within the meaning of Article 7:87 of the Belgian Companies and Associations Code. The chairperson of the audit committee is to be appointed by the members of the audit committee. The composition of the audit committee complies with the 2009 Code and the 2020 Code, which require that a majority of the members of the audit committee are independent.

The members of the audit committee must have a collective competence in the business activities of the Company as well as in accounting, auditing and finance, and at least one member of the audit committee must have the necessary competence in accounting and auditing. According to the Board of Directors, the members of the audit committee satisfy this requirement, as evidenced by the different senior management and Director mandates that they have held in the past and currently hold.

The role of the audit committee is to assist the Board of Directors in fulfilling its financial, legal and regulatory monitoring responsibilities. The committee reports regularly to the Board of Directors on the exercise of its duties, identifying any matters in respect of which it considers that action or improvement is needed, and making recommendations as to the steps to be taken. The audit review and the reporting on that review cover the Company and its subsidiaries as a whole. The specific tasks of the audit committee are outlined in the Company's governance charter and include the following:

- to inform the Board of Directors of the result of the audit of the financial statements and the manner in which the audit has contributed to the integrity of the financial reporting and the role that the audit committee has played in that process;
- to monitor the financial reporting process, and to make recommendations or proposals to ensure the integrity of the process;
- to monitor the effectiveness of the Company's internal control and risk management systems, and the Company's internal audit process and its effectiveness;
- to monitor the audit of the annual statutory and consolidated financial statements, including the follow-up questions and recommendations by the statutory auditor and, as the case may be, the auditor responsible for the audit of the consolidated financial statements;
- to assess and monitor the independence of the statutory auditor, in particular with respect to the appropriateness of the provision of additional services to the Company. More specifically, the audit committee analyses, together with the statutory auditor, the threats for the statutory auditor's independence and the security measures taken to limit these threats, when the total amount of fees exceeds the criteria specified in Article 4 §3 of Regulation (EU) No 537/2014; and
- to make recommendations to the Board of Directors on the selection, appointment and remuneration of the Company's statutory auditor in accordance with Article 16 § 2 of Regulation (EU) No 537/2014.

The following Non-Executive Directors are members of the audit committee in 2019: Hilde Windels BV, represented by its permanent representative, Ms. Hilde Windels (chair), Qaly-Co BV, represented by its permanent representative, Dr. Lieve Verplancke, and Valiance Advisors LLP, represented by its permanent representative, Mr. Jan Pensaert. As required by law, the chair of the audit committee is competent in accounting and auditing, as is evidenced by her role chief executive officer, chief financial officer and Non-Executive Director of multiple life sciences companies.

The audit committee is a collegial body and deliberates and makes decisions as such. The audit committee met 4 times in 2019. All members of the audit committee were present or represented at all meetings.

## Nomination and Remuneration Committee

According to Article 7:100 §4 of the Belgian Companies and Associations Code, MDxHealth would meet the size criteria in order to operate without a separate remuneration committee, but the Company has chosen to continue operating with a separate remuneration committee.

MDxHealth's nomination and remuneration committee must be composed of at least three members and must be composed exclusively of Non-Executive Directors who have the necessary competence in terms of remuneration policy. A majority of its members must be Independent Directors. The nomination and remuneration committee is chaired by the chairman of the Board of Directors or another Non-Executive Director appointed by the committee. The chairman of the Board of Directors should not chair the committee when dealing with the designation of his successor. The CEO should participate in an advisory capacity in the meetings of the committee when it deals with the remuneration of other executive managers.

The role of the nomination and remuneration committee is to make recommendations to the Board of Directors with regard to the appointment and remuneration of Directors and members of the executive management and, in particular, to:

- identify, recommend and nominate, for the approval of the Board of Directors, candidates to fill vacancies in the Board of Directors and executive management positions as they arise. In this respect, the nomination and remuneration committee must consider and advise on proposals made by relevant parties, including management and shareholders;
- advise the Board of Directors on any proposal for the appointment of the chief executive officer and on the chief executive officer's proposals for the appointment of other members of the executive management;
- draft appointment procedures for members of the Board of Directors and the chief executive officer;
- ensure that the appointment and re-election process is organized objectively and professionally;
- periodically assess the size and composition of the Board of Directors and make recommendations to the Board of Directors with regard to any changes;
- consider issues related to succession planning;
- make proposals to the Board of Directors on the remuneration policy for Directors and members of the executive management and the persons responsible for the day-to-day management of the Company, as well as, where appropriate, on the resulting proposals to be submitted by the Board of Directors to the shareholders' meeting;
- make proposals to the Board of Directors on the individual remuneration of Directors and members of the executive management, and the persons responsible for the day-to-day management of the Company, including variable remuneration and long-term incentives, whether or not share-related, in the form of share options or other financial instruments, and arrangements on early termination, and where applicable, on the resulting proposals to be submitted by the board of directors to the shareholders' meeting;
- prepare a remuneration report to be included by the Board of Directors in the annual corporate governance statement;
- present and provide explanations in relation to the remuneration report at the annual shareholders' meeting; and
- report regularly to the Board of Directors on the exercise of its duties.

The following Non-Executive Directors are members of the nomination and remuneration committee: TSTILL Enterprises LLC, represented by its permanent representative, Mr. Timothy Still (chair), assuming the role of Chair following the resignation of Lab Dx L.L.C., represented by Mr. Walter Narajowski, from the Board of Directors effective October 30, 2019; Gengest BV, represented by Mr. Rudi Mariën; Qaly-Co BV, represented by its permanent representative, Dr. Lieve Verplancke; Ahok BV, represented by its permanent representative, Mr. Koen Hoffman, and Valiance Advisors LLP, represented by its permanent representative, Mr. Jan Pensaert.

The nomination and remuneration committee is a collegial body and deliberates and makes decisions as such.

The nomination and remuneration committee met 2 times in 2019. All of the committee members attended all of the committee meetings. Neither Valiance Advisors LLP nor Ahok BV attended the two meetings of the nomination and remuneration committee held in 2019, as they occurred prior to their becoming members of the committee.

## **Process for Evaluating the Board, its Committees, and its Individual Directors**

At least every three years the Board of Directors will, under the lead of its Chairman, assess, through a formal process, its own performance and its interaction with the executive management, as well as its size, composition, performance and those of its committees, as well as the contribution of each Director.

This evaluation process has five objectives:

1. assessing how the Board of Directors and its committees operate,
2. checking that the important issues are suitably prepared and discussed,
3. checking the Board's and committees' current composition against the desired composition,
4. evaluating the actual contribution of each Director's work, the Director's presence at Board and committee meetings and his involvement in discussions and decision-making, and
5. evaluating whether the fees and costs of the full Board and individual Directors is in line with the performance of the Company and the performance of the individual Director.

The Chairman can organize an individual meeting with each Director to discuss these items, including each Director's own performance and the performance of its colleague Directors. The conclusions resulting from these individual meetings will be submitted to the Board by the Chairman.

At the end of each Board member's term, the nomination and remuneration committee should evaluate this Board member's presence at the Board or committee meetings, their commitment and their constructive involvement in discussions and decision-making in accordance with a pre-established and transparent procedure. The nomination and remuneration committee should also assess whether the contribution of each Board member is adapted to changing circumstances.

The Board will act on the results of the performance evaluation. Where appropriate, this will involve proposing new Board members for appointment, proposing not to re-appoint existing Board members or taking any measure deemed appropriate for the effective operation of the Board.



# Executive Management



## Executive management

The Board of Directors has appointed the executive management of the Company. The terms of reference of the executive management have been determined by the Board of Directors in close consultation with the CEO.

### Chief Executive Officer

The CEO is appointed, and can be removed, by the Board of Directors of the Company.

The CEO is charged by the Board of Directors with the day-to-day management of the Company and is therefore also also managing Director of the Company. In this function, the CEO has the following general responsibilities:

- the implementation of the decisions of the Board of Directors, within the strategy, planning, values and budgets approved by the Board of Directors,
- overseeing the different central departments and business units of the Company, and reporting to the Board of Directors on their activities,
- the development of proposals for the Board of Directors relating to strategy, planning, finances, operations, human resources and budgets, and other matters that are to be dealt with at the level of the Board of Directors.

The specific tasks of the CEO are further described in the corporate governance charter.

### Other Members of Executive Management Team

The other members of the executive management team, being the heads of the main activities and central departments (and their divisions) of MDxHealth, are appointed and removed by the CEO in close consultation with the Board of Directors of the Company.

The main tasks of the executive management are to organize their department in accordance with the guidelines determined by the CEO and to report to the CEO on the operation and activities of their department.

## Composition of the Management Team

The composition of the Management Team is set out below and reflects the situation at the date of this Annual Report:

<b>Name</b>	<b>Age on Dec 31, 2019</b>	<b>Position</b>	<b>Permanent Address</b>
<i>Mr. Michael K. McGarrity</i>	<i>56</i>	<i>Chief Executive Officer</i>	<i>15279 Alton Parkway Ste 100, Irvine, CA 92618 USA</i>
<i>Mr. John Bellano</i>	<i>51</i>	<i>Chief Commercial Officer</i>	<i>15279 Alton Parkway Ste 100, Irvine, CA 92618 USA</i>
<i>Mr. Ron Kalfus</i>	<i>45</i>	<i>Chief Financial Officer</i>	<i>15279 Alton Parkway Ste 100, Irvine, CA 92618 USA</i>
<i>Mr. Joseph Sollee</i>	<i>55</i>	<i>Executive Vice President, General Counsel &amp; Chief Compliance Officer</i>	<i>15279 Alton Parkway Ste 100, Irvine, CA 92618 USA</i>

In 2019 the Management Team consisted of Mr. Michael McGarrity, as CEO (who joined on February 18, 2019), Mr. Ron Kalfus, as CFO (who joined on July 22, 2019), Mr. John Bellano, as Chief Commercial Officer (who joined on June 17, 2019), Mr. Joseph Sollee, as Executive Vice President of Corporate Development, General Counsel & Chief Compliance Officer, Dr. Jan Groen, former CEO (who resigned with effect as of February 18, 2019), and Marcofin BV, represented by its permanent representative, Jean-Marc Roelandt, former CFO (who whose mandate ended on June 30, 2019).

The executive management did not constitute an executive committee (comité de direction / directiecomité) within the meaning of the former Article 524 bis of the Belgian Company Code.

Following are biographies of the executive management team members (also referred to as executives) as of the date of this Annual Report:

### **Mr. Michael K. McGarrity, Chief Executive Officer**

See “Board of Directors - Composition of the Board of Directors”.

### **Mr. John Bellano, Chief Commercial Officer**

Mr. Bellano joined MDxHealth in June 2019. He has more than 25 years of experience in the healthcare Industry. Mr. Bellano started his career in pharmaceuticals and transitioned to molecular diagnostics where he has spent the past 20 years of his career, most recently as Chief Commercial Officer of Sterilis Solutions Prior to Sterilis Solutions he served as the commercial leader for pharmacogenomic companies Assurex Health and AltheaDx. While at Assurex Health (Myriad Genetics) revenue grew from \$700k to a run rate of \$100 Million during his 5-year span with the organization.

**Ron Kalfus, Chief Financial Officer**

Mr. Kalfus joined MDxHealth in July 2019. He has over 20 years of leadership experience in both public and private companies within diagnostics/biotech and other sectors, and brings extensive knowledge in financial operations and management. Mr. Kalfus joined MDxHealth from Rosetta Genomics, where he helped lead efforts to reposition the company for commercial success with its oncology diagnostic products, and raised over \$60 million in capital to fund these efforts. Prior to Rosetta, Mr. Kalfus served as the CFO and Treasurer of MabCure, a Belgium-based publicly-traded biotechnology startup in the field of early cancer detection using antibodies.

**Mr. Joseph Sollee, Executive Vice President, General Counsel & Chief Compliance Officer**

Mr. Sollee has provided legal counsel to MDxHealth since its inception in 2003, and in April 2008 joined our management team. Prior to joining the Company, Mr. Sollee served as Special Counsel with the law firm of Kennedy Covington (now K&L Gates), where he led the Life Sciences Practice Group. Mr. Sollee has more than 20 years of experience in the life sciences industry, and has held senior legal and management positions at Triangle Pharmaceuticals and TherapyEdge. In addition, he has practiced as a corporate attorney in the Washington D.C. legal firm Swidler & Berlin and in investment banking at Smith Barney in New York. Mr. Sollee received a Juris Doctorate in Law (JD) and a Master's degree in International & Comparative Law (LLM) from Duke University, a BA degree from Harvard University, and has been certified into the legal bars of New York, Washington D.C. and North Carolina.

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# Dealing Code

The rules and procedures that apply when Board members and executive managers deal in MDxHealth securities are defined in the Company's Dealing Code. The code prohibits Board members and executive managers from dealing with MDxHealth securities during periods prohibited by applicable laws and regulation or during specific closed periods announced by the Company. The dealing code is available in its entirety on the Company's website ([www.mdxhealth.com](http://www.mdxhealth.com)).

## Internal Control and Risk Management

### A. INTRODUCTION

The Company operates a risk management and control framework in accordance with the Belgian Companies and Associations Code and the 2020 Code. MDxHealth is exposed to a wide variety of risks within the context of its business operations that can result in its objectives being affected or not achieved. Controlling those risks is a core task of the Board of Directors (including the audit committee), the executive management and all other employees with managerial responsibilities.

The risk management and control system has been set up to reach the following goals:

- achievement of the Company's objectives;
- achieving operational excellence;
- ensuring correct and timely financial reporting; and
- compliance with all applicable laws and regulations.

### B. CONTROL ENVIRONMENT

#### Three lines of defense

The Company applies the 'three lines of defense model' to clarify roles, responsibilities and accountabilities, and to enhance communication within the area of risk and control. Within this model, the lines of defense to respond to risks are:

- First line of defense: line management is responsible for assessing risks on a day-to-day basis and implementing controls in response to these risks.
- Second line of defense: the oversight functions like Finance and Controlling and Quality and Regulatory oversee and challenge risk management as executed by the first line of defense. The second line of defense functions provide guidance and direction and develop a risk management framework.
- Third line of defense: independent assurance providers such as external accounting and external audit challenge the risk management processes as executed by the first and second line of defense.



## Policies, procedures and processes

The Company fosters an environment in which its business objectives and strategy are pursued in a controlled manner.

This environment is created through the implementation of different Company-wide policies, procedures and processes such as the Company's values, the Quality Management System and the Delegation of Authorities rule set.

The employees are regularly informed and trained on these subjects in order to develop sufficient risk management and control at all levels and in all areas of the organization.

## C. RISK MANAGEMENT

Sound risk management starts with identifying and assessing the risks associated with the Company's business and external factors. Once the relevant risks are identified, the Company strives to prudently manage and minimize such risks, acknowledging that certain calculated risks are necessary to ensure that the Company achieves its objectives and continues to create value for its stakeholders. All employees of the Company are accountable for the timely identification and qualitative assessment of the risks within their area of responsibility.

## D. CONTROL ACTIVITIES

Control measures are in place to minimize the effect of risks on the Company's ability to achieve its objectives. These control activities are embedded in the Company's key processes and systems to assure that the risk responses and the Company's overall objectives are carried out as designed. Control activities are conducted throughout the organization, at all levels and within all departments.

## E. INFORMATION AND COMMUNICATION

The Company recognizes the importance of timely, complete and accurate communication and information both top down as well as bottom-up. The Company therefore put several measures in place to assure amongst others:

- security of confidential information;
- clear communication about roles and responsibilities; and
- timely communication to all stakeholders about external and internal changes impacting their areas of responsibility.

## F. MONITORING OF CONTROL MECHANISMS

Monitoring helps to ensure that internal control systems operate effectively. The quality of the Company's risk management and control framework is assessed by the following functions:

- **Quality and Regulatory:** All employees of the Company are instructed on the rules and policies of the Company via a booklet of work rules, the terms of their employment arrangements, standard operating procedures defined by task/area, and by numerous documents (such as the Code of Business Conduct and Ethics and the Dealing Code) that are distributed and explained to the personnel.
- **External Audit:** In the Company's review of the annual accounts, the statutory auditor focuses on the design and effectiveness of internal controls and systems relevant for the preparation of the financial statements. The outcome of the audits, including work on internal controls, is reported to management and the audit committee.
- **Audit Committee:** The Board of Directors and the audit committee have the ultimate responsibility with respect to internal control and risk management.

In addition, the legal department of MDxHealth, under supervision of the CEO and together with the management team, has set up internal procedures in order to ensure that acts performed within or by the Company are in compliance with the existing laws and external regulations. The management is also responsible to comply with internal regulations and the Board of Directors is ensuring that the management is respecting the general policies and the corporate plans.

The Board of Directors has established a Code of Business Conduct and Ethics to aid MDxHealth's directors, officers and employees in making ethical and legal decisions when conducting Company business and performing their day-to-day duties. The Code of Business Conduct and Ethics is available in its entirety on the Company's website ([www.mdxhealth.com](http://www.mdxhealth.com)). In addition, the Board has appointed a Chief Compliance Officer to oversee ongoing compliance with the Code of Business Conduct and Ethics and existing laws and external regulations, and to report regularly to the Board of Directors and the Audit Committee on compliance matters.

#### **G. RISK MANAGEMENT AND INTERNAL CONTROL WITH REGARD TO THE PROCESS OF FINANCIAL REPORTING**

The accurate and consistent application of accounting rules throughout the Company is assured by means of set of control procedures, including:

- The Audit Committee reviews all financial information before it is released
- The Board of Directors reviews internal monthly financial information
- The financial auditors not only audit the year-end financial statements, but at the request of the Company they also perform a limited review of the Interim half-year financial statements
- The Company managers and finance department personnel explain all material variances in historical figures and between the budget and actual figures
- The Board of Directors, the Company managers and finance department personnel perform reviews and controls of the key financial figures at each reporting period, some of which are described below
- At the Board of Directors level, there is a periodic review and approval of the following main topics:
  - Overall strategy and strategic options;
  - Multi-year business plan and company goals;
  - Ensuing year budget and targets;
  - Comparison of actual results and budgeted figures;
  - Hiring, motivation, and retention of key talent;
  - Remuneration and benefits;
  - Financial statements; and
  - Internal controls.

Management of the Company is organized on the basis of plans, departments, projects, and corresponding budgets and targets. Progress on the core projects, budgets, and plans are reviewed on a periodic basis. The management has clearly aligned responsibilities as described in the job descriptions which are prepared for all employees of the Company.

A set of measures has been taken to assure the quality of the financial and management information, amongst others:

- The appointment of qualified personnel in key positions with all entities of the Company;
- The definition of a set of standard procedures for key activities such as steps for the approval, purchasing and payment of services and goods;
- The request for the external auditors to pay special attention to areas with specific company and industry risk;
- The request for specialized consultants to assist in designing and/or reviewing key procedures, systems, or reports;
- The audit committee or individual Directors periodically review and are consulted on key matters and procedures and when needed external specialist assistance is sought.

The Board periodically reviews and provides instructions to the management team on how to manage credit risks, interest risks, exchange risks, and liquidity risks. As an example, the Board has given instructions on what type of financial instruments the Company can place its cash and on which it is not allowed to do so. The management also seeks external specialized advice on managing such risks.

## Principal Shareholders

The Company has a wide shareholder base, mainly composed of institutional investors in European countries.

The table below provides an overview of the shareholders that notified the Company, of their shareholding in the Company pursuant to applicable transparency disclosure rules, up to the date of this report. Although the applicable transparency disclosure rules require that a disclosure be made by each person passing or falling under one of the relevant thresholds, it is possible that the information below in relation to a shareholder is no longer up to date.

	Date of Notification	% of the voting rights attached to Shares <sup>(1)</sup>
Biovest NV <sup>(2)</sup>	July 1, 2015	13.99%
Valiance Asset management Limited <sup>(3)</sup>	October 8, 2019	15.82%
Scorpiaux BV <sup>(4)</sup>	September 27, 2019	5.48%

Notes:

<sup>(1)</sup> The percentage of voting rights is calculated as per the date of the relevant notification and taking into account the total number of outstanding shares of the Company as of such date.

<sup>(2)</sup> Biovest NV (formerly Biovest [Comm.Va](#)), informed the Company, by means of a notification dated July 1, 2015, that the aggregate shareholding of the Biovest [Comm.Va](#) had passively crossed the threshold of 15% of the outstanding voting rights of the Company on July 1, 2015. The notification specified furthermore that Biovest NV is controlled by Rudi Mariën.

<sup>(3)</sup> Valiance Asset Management Limited, informed the Company, by means of a notification dated October 8, 2019, that the aggregate shareholding of Valiance Asset Management Limited, through three different entities (Valiance Holdings Limited, Valiance Life Sciences Growth Investment Fund SICAV-SIF, and TopMDx Ltd.), had crossed the threshold of 15% of the outstanding voting rights of the Company on October 8, 2019. The notification specified furthermore that Valiance Asset Management Limited can exercise the voting rights at its discretion for each of these 3 entities and that Valiance Assent Management Limited is not a controlled entity.

<sup>(4)</sup> Scorpiaux BV, informed the Company, by means of a notification dated October September 27, 2019, that the aggregate shareholding of Scorpiaux BV crossed the threshold of 5% of the outstanding voting rights of the Company on September 27, 2019. The notification specified furthermore that Scorpiaux BV is exclusively controlled in the meaning of Article 5 and 7 of the Belgian Companies Code by Bart Versluys and that Scorpiaux BV exercise, together with a third party, control in the meaning of Article 5 and 7 of the Belgian Companies Code over Versluys Invest BV.

No other shareholders, alone or in concert with other shareholders, notified the Company of a participation or an agreement to act in concert in relation to 3% or more of the current total existing voting rights attached to the voting securities of the Company.

Copies of the abovementioned transparency notifications, are available on the Company's website (<https://mdxhealth.com/>).

## Share Capital and Shares

On the date of this report, the share capital of the Company amounts to EUR 56,260,102.01 and is fully paid-up. It is represented by 70,528,525 ordinary shares, each representing a fractional value of (rounded) EUR 0.7977 and representing one 70,528,525th of the share capital. The Company's shares do not have a nominal value.

In addition to the outstanding shares, the Company has a number of outstanding options that are exercisable into ordinary shares, consisting of:

- 65,000 outstanding share options, issued under the form of subscription rights on March 15, 2012;
- 360,000 outstanding share options, issued under the form of subscription rights on June 15, 2012;
- 853,562 outstanding share options issued under the form of subscription rights on June 23, 2014 (of which 68,500 stock options have not yet been granted);
- 2,060,125 outstanding share options issued under the form of subscription rights on June 19, 2017 (of which 271,000 stock options have not yet been granted); and
- 2,990,000 outstanding share options issued under the form of subscription rights on June 21, 2019 (of which 1,940,000 stock options have not yet been granted).

## Form and Transferability of the Shares

The shares of the Company can take the form of dematerialized shares. All the Company's shares are fully paid-up and are freely transferable. All of the 70,528,525 existing shares have been admitted to trading on the regulated market of Euronext Brussels.

## Currency

The Company's shares do not have a nominal value, but each reflect the same fraction of the Company's share capital, which is denominated in euro.

## Voting Rights attached to the Shares

Each shareholder of the Company is entitled to one vote per share. Shareholders may vote by proxy, subject to the rules described in the Company's articles of association.

Voting rights can be mainly suspended in relation to shares:

- which are not fully paid up, notwithstanding the request thereto of the Board of Directors of the Company;
- to which more than one person is entitled or on which more than one person has rights in rem on, except in the event a single representative is appointed for the exercise of the voting right;
- which entitle their holder to voting rights above the threshold of 3%, 5%, 10%, 15%, 20% and any further multiple of 5% of the total number of voting rights attached to the outstanding financial instruments of the Company on the date of the relevant general shareholders' meeting, in the event that the relevant shareholder has not notified the Company and the FSMA at least 20 calendar days prior to the date of the general shareholders' meeting in accordance with the applicable rules on disclosure of major shareholdings; and
- of which the voting right was suspended by a competent court or the FSMA.

Pursuant to the Belgian Companies and Associations Code, the voting rights attached to shares owned by the Company, or a person acting in its own name but on behalf of the Company, or acquired by a subsidiary of the Company, as the case may be, are suspended.

## Dividends and Dividend Policy

All of the shares of the Company entitle the holder thereof to an equal right to participate in dividends in respect of the financial year ending December 31, 2019 and future years. All of the shares participate equally in the Company's profits (if any). Pursuant to the Belgian Companies and Associations Code, the shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the annual general shareholders' meeting, based on the most recent statutory audited financial statements, prepared in accordance with Belgian GAAP and based on a (non-binding) proposal of the Company's Board of Directors. The Belgian Companies and Associations Code and the Company's articles of association also authorize the Board of Directors to declare interim dividends without shareholder approval. The right to pay such interim dividends is, however, subject to certain legal restrictions.

The Company's ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law on the basis of the Company's stand-alone statutory accounts prepared in accordance with Belgian GAAP. In particular, dividends can only be distributed if following the declaration and issuance of the dividends the amount of the Company's net assets on the date of the closing of the last financial year as follows from the statutory non-consolidated financial statements (i.e. summarized, the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities, all in accordance with Belgian accounting rules), decreased with, except in exceptional cases, to be disclosed and justified in the notes to the annual accounts, the non-amortized costs of incorporation and extension and the non-amortized costs for research and development, does not fall below the amount of the paid-up capital (or, if higher, the issued capital), increased with the amount of non-distributable reserves.

In addition, pursuant to Belgian law and the Company's articles of association, the Company must allocate an amount of 5% of its Belgian GAAP annual net profit (nettowinst/bénéfices nets) to a legal reserve in its stand-alone statutory accounts, until the legal reserve amounts to 10% of the Company's share capital. The Company's legal reserve currently does not meet this requirement. Accordingly, 5% of its Belgian GAAP annual net profit during future years will need to be allocated to the legal reserve, limiting the Company's ability to pay out dividends to its shareholders.

## Information that has an impact in case of public takeover bids

The Company provides the following information in accordance with Article 34 of the Belgian Royal Decree dated November 14, 2007:

- (i) The share capital of the Company amounts to EUR 56,260,102.01 and is fully paid-up. It is represented by 70,528,525 ordinary shares, each representing a fractional value of (rounded) EUR 0.7977 and representing one 70,528,525th of the share capital. The Company's shares do not have a nominal value.
- (ii) Other than the applicable Belgian legislation on the disclosure of significant shareholdings and the Company's articles of association, there are no restrictions on the transfer of shares.
- (iii) There are no holders of any shares with special control rights.
- (iv) There are no share option plans for employees other than the share option plans disclosed elsewhere in this report. These share option plans contain provisions on accelerated vesting in case of change of control.
- (v) Each shareholder of the Company is entitled to one vote per share. Voting rights may be suspended as provided in the Company's articles of association and the applicable laws and articles.
- (vi) There are no agreements between shareholders which are known by the Company that may result in restrictions on the transfer of securities and/or the exercise of voting rights.
- (vii) The rules governing appointment and replacement of Board members and amendment to articles of association are set out in the current versions of the Company's articles of association and the Company's Corporate Governance Charter.
- (viii) The powers of the Board of Directors, more specifically with regard to the power to issue or redeem shares are set out in the Company's articles of association. The Board of Directors was not granted the authorization

to purchase its own shares «to avoid imminent and serious danger to the Company» (i.e., to defend against public takeover bids). The Company's articles of association do not provide for any other specific protective mechanisms against public takeover bids.

- (ix) At the date of this report, the Company is a party to the following significant agreements which, upon a change of control of the Company or following a takeover bid can enter into force or, subject to certain conditions, as the case may be, can be amended, be terminated by the other parties thereto or give the other parties thereto a right to an accelerated repayment of outstanding debt obligations of the Company under such agreements:
- The Company has borrowed an amount equal to EUR 9,000,000, as of November 1, 2019, under a senior secured loan agreement with Kreos Capital. The main characteristics of the loan agreement can be summarized as follows:
  - Term: A 48-month term, consisting of first 12 months interest payments only and subsequently 36 months equal monthly instalments of principal and interest. If certain conditions are satisfied, the interest only period can be extended to 18 months (with the principal and interest period reduced to 30 months);
  - Interest: The loan accrues interest at a rate of 9.5% per annum;
  - Fees: A number of fees will be payable to Kreos Capital, consisting notably of (i) a transaction fee equal to EUR 112,500, (ii) a drawdown fee equal to 7% of the amount drawn down under the loan agreement, which will not be payable in cash but shall remain outstanding as a "convertible loan" (see below), and (iii) an end of loan payment upon final repayment of the loan, equal to 5% of the amount drawn down under the loan agreement;
  - Convertible loan: Upon drawdown of the loan, the 7% drawdown fee will not be paid in cash but shall remain outstanding as a convertible loan. The convertible loan will not accrue interest and will not require any amortization or repayment. The Company will not have the right to prepay or otherwise terminate the convertible loan. The convertible loan expires on the earlier of (i) the tenth anniversary of the drawdown of the loan and (ii) the sale of the entire issued share capital of MDxHealth (the "Expiration Date");
  - Conversion of the convertible loan: Upon the Expiration Date, the convertible loan will convert automatically into ordinary shares. Prior to the Expiration Date, Kreos Capital may at any time convert the convertible loan into new ordinary shares at a ratio equal to the lower of (i) 100% of the volume weighted average share price during the 30-day period ending ten days prior to the first drawdown of the loan, and (ii) the price per share paid in the Capital Increase;
  - Cancellation of the convertible loan: In lieu of converting the convertible loan, Kreos Capital may instead cancel the convertible loan at any time after the earlier to occur of (i) repayment or prepayment in full of the loan, and (ii) sale of the entire issued share capital of MDxHealth, but before the Expiration Date, cancel the convertible loan. In such case, Kreos Capital will be paid an amount equal to 150% of the principal amount of the convertible loan;
  - Board observer: Kreos Capital will be entitled to appoint a non-voting board observer;
  - Change of control: The loan agreement contains a change of control clause and the loan agreement requires such to be approved by the Company's shareholders by no later than the annual general meeting to be held in 2020;
  - Collateral: Security has been granted over all assets owned by MDxHealth and its subsidiaries, including IP rights (but excluding any shares in, and IP rights licensed to, MDxHealth or its subsidiaries);
  - Contractual restrictions: The loan agreement does not contain financial covenants, but it does contain other customary restrictions on the business of MDxHealth and its subsidiaries (such as limitations on future disposals, financial indebtedness, security and acquisitions subject to certain carve-outs and limitations).

No takeover bid has been instigated by third parties in respect of the Company's equity during the current financial year.

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# Statutory auditor

## Services performed by the auditor and performance of exceptional activities or execution of special instructions (Article 3:65 Belgian Companies and Associations Code)

BDO Réviseurs d'Entreprises. SCRL, a cooperative company with limited liability (société coopérative à responsabilité limitée/coöperatieve vennootschap met beperkte aansprakelijkheid) organized and existing under the laws of Belgium, with registered office at Da Vincilaan 9, 1930 Zaventem, Belgium, was re-appointed on May 26, 2017 as the statutory auditor of the Company for a term of 3 years ending immediately after the closing of the annual shareholders' meeting to be held in 2020. Mr. Gert Claes has represented BDO since May 29, 2015.

The statutory auditor and the auditor responsible for the audit of the consolidated financial statements, confirms annually in writing to the audit committee his or her independence from the Company, discloses annually to the audit committee any additional services provided to the Company, and discusses with the audit committee the threats to his or her independence and the safeguards applied to mitigate those threats as documented by him or her.

During the past fiscal year, in addition to their usual activity, the statutory auditor performed additional activities on behalf of the Company mainly for the issuance of special reports related to warrant plans, grant report certification, for participation to the audit committees and for participation to special projects.

The Company expensed €111,000 (USD equivalent \$125,000) in fees to the auditor in 2019. The fees are broken down as follows:

- Audit fee for statutory and consolidated financials of € 99,000 (\$111,000)
- Audit related services (legal missions) € 12,000 (\$14,000)

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# Remuneration report

The following remuneration report has been prepared by the nomination and remuneration committee and approved by the Board of Directors of MDxHealth on April 23, 2020. This remuneration report is part of the Corporate Governance Statement, which is part of the Company's annual report of the Board of Directors on the statutory accounts for the financial year ended on December 31, 2019 in accordance to in Article 3:6, §3 of the Belgian Companies and Associations Code (the "Remuneration Report"). The Company has reviewed the remuneration policy of its management, Executive and Non-Executive Directors in light of Article 3:6 of the Belgian Companies and Associations Code, as supplemented by the relevant provisions of the 2009 Code and the 2020 Code, and has prepared this Remuneration Report in accordance with the requirements contained therein.

## Procedure adopted in 2019 to develop a remuneration policy

During 2019, MDxHealth has continued to apply the remuneration policy first adopted in 2012. In conformity with the applicable legislation, the nomination and remuneration committee of the Board of Directors, composed of Non-Executive members of the Board, has the tasks (i) to formulate proposals on the remuneration policy applicable to Directors, managers and other executives, as well as on the determination of their remuneration on an individual basis, and (ii) to prepare the remuneration report to be inserted in the corporate governance statement of the annual report.

The remuneration report will be submitted to a vote by the annual general shareholders' meeting. The main recommendations seek to align the interests of the Board members with the goals of the Company, and can be summarized as follows:

- the setting in place of a cash only remuneration scheme for Non-Executive Independent Directors.
- the non-granting of fees to Non-Independent Directors for serving on the Board;
- the demand (but not the request) to Independent Directors serving as representatives of investors that (as the case may be) own an amount of Company shares greater than the five percent (5%) transparency filing threshold to waive their Board fees;
- the change from the variable component of Board remuneration to a fixed annual compensation scheme.

In 2019, as mentioned above, share options have been granted to Non-Executive Directors (including to Independent Directors). This was contrary to provision 7.7 of the 2009 Code, which provide that Non-Executive Directors should not be entitled to performance-related remuneration such as, amongst others, share-related long-term incentive schemes. The Company believed that these provisions of the 2009 Code were not appropriate and adapted to take into account the realities of companies in the biotech and life sciences industry that are still in a development phase. Notably, the ability to remunerate Non-Executive Directors with share options allowed the Company to limit the portion of remuneration in cash that the Company would otherwise need to pay to attract or retain renowned experts with the most relevant skills, knowledge and expertise. The Company was of the opinion that granting Non-Executive Directors the opportunity to be remunerated in part in share-based incentives rather than all in cash enabled the Non-Executive Directors to link their effective remuneration to the performance of the Company and to strengthen the alignment of their interests with the interests of the Company's shareholders. The Company believed that this was in the interest of the Company and its stakeholders. Furthermore, the Company believed that this was customary for Directors active in companies in the life sciences industry. In any event, as from the financial year started on January 1, 2020, the Company will no longer grant share options to Independent Directors.

## Procedure adopted in 2019 to determine the level of remuneration

### Directors

Annually, the nomination and remuneration committee reviews the fee levels paid to Directors and compares them to fee levels paid at other comparable companies.

Grants of subscription rights to Directors were recommended by the non-conflicted members of the nomination and remuneration committee, reviewed by the Board of Directors and submitted to the general shareholders' meeting for approval. The number of subscription rights granted in the past to Non-Executive Directors (including Independent Directors) has remained low compared to the number of total outstanding security instruments. Non-Executive Directors (including Independent Directors) are not entitled to bonuses, fringe benefits or pension benefits.

Non-Executive Board members who provide services to the Company outside of the formal Board meetings or Board committee meetings, must have their work and fees pre-approved by the non-conflicted members of the nomination and remuneration committee. These fees are then submitted for approval at the ensuing annual general shareholders' meeting.

For the executive Director position, the nomination and remuneration committee proposes remuneration changes and bonuses, if any to the Board of Directors for approval.

### CEO and Managers

The remuneration of the executive management is designed to attract, retain and motivate executive managers. The level and structure of the remuneration are subject to an annual review by the nomination and remuneration committee to take into account market practice. The annual review does not provide mechanisms for automatic adjustments, except for changes that are legally required.

The fixed remuneration level, the variable bonus, and the objectives of the CEO are reviewed by the nomination and remuneration committee, compared to industry and market levels, and confirmed by the Board of Directors. The Board of Directors sets the Company objectives and the personal objectives of the CEO.

The CEO sets the personal objectives of the other executive managers. He recommends grants of subscription rights, bonuses and changes, if any, in the fixed remuneration of executive managers to the nomination and remuneration committee. The nomination and remuneration committee reviews these recommendations and compares them to industry and market practices. It then proposes the warrant grants, bonuses and remuneration changes, if any, to the Board of Directors, and to the extent required by applicable law, to the general shareholders' meeting, for approval.

## Declaration on the remuneration policy

### Remuneration policy in 2019

The Board of Directors determines, upon recommendation of the nomination and remuneration committee, the remuneration policy for Directors and Managers.

## Directors

The remuneration policy for Non-Executive and executive Directors was modified at the annual shareholders' meeting of May 25, 2012, and remained in effect for the accounting year 2019.

- Non-Executive Directors

The Non-Executive Directors are remunerated on the basis of a pre-defined fixed annual retainer fee. The fee level is the applicable fixed annual retainer fee approved at the last annual general shareholders' meeting concerning this matter, i.e.:

- €35,000 (USD equivalent \$39,183)<sup>1</sup> for the Chair of the Board of Directors;
- €30,000 (\$33,585)<sup>1</sup> for the Chair of the Audit Committee;
- €28,000 (\$31,346)<sup>1</sup> for the Chair of the Nomination and Remuneration Committee; and
- €25,000 (\$27,988)<sup>1</sup> for any other Director.

A record of Board attendance is maintained by the secretary to the Board of Directors. This record is then reviewed by the Board of Directors and confirmed by the approval of the Board minutes. Regular attendance at scheduled meetings of the Board of Directors, including committee meetings, is expected. In the event that a Director fails to attend at least 75% of the scheduled meeting of the Board of Directors during a calendar year, the Board may reduce such Director's applicable annual retainer fee by a pro rata amount to reflect actual attendance.

Apart from the above remuneration, Directors will be entitled to a reimbursement of out of pocket expenses actually incurred to participate to Board meetings.

Although all Non-Executive Directors have the right to receive the foregoing applicable annual retainer fee, the Board suggests that each Non-Independent Director elect, in his or her discretion, to waive its right to receive such fees. In calendar year 2019, the two Non-Independent Directors, who have not held an executive position within the Company, agreed to waive their Director's fees.

The mandate of Non-Executive Directors can be terminated at any time without any compensation. Non-Executive Directors do not receive any form of pension plan benefits from the Company. The Company has not made any loans to the members of the Board of Directors.

<sup>1</sup> exchange rate 1€ = 1.1195\$ (historical rate 2019)



- Executive Directors

Executive Directors do not receive any remuneration for their position as a Director. Executive Directors are only remunerated for their role as executive managers. These individuals receive a fixed remuneration plus a variable bonus that is linked to their personal achievements and the achievements of the Company. They do not receive any additional remuneration for the exercise of their Board mandate. The mandate of executive Directors may be terminated at any time without any form of compensation. Their remuneration package is approved by the general shareholders' meeting. The CEO is the only executive Director of the Board of Directors of the Company and he does not earn any remuneration in respect of his executive Director position.

- Relative importance of the components of remuneration

The relative importance of the various components of remuneration as referred to in article 96, §3, al. 2, 2°, b) of the Belgian Company Code, is provided below under the "Remuneration Amounts for the Reported Year" section of this Remuneration Report.

## CEO and Managers

Each member of the executive management is entitled to a basic fixed remuneration designed to fit responsibilities, relevant experience and competences, in line with market rates for equivalent positions. The majority of the annual remuneration is a fixed compensation amount. There is no minimum or maximum variable bonus.

The CEO has a fixed remuneration, a fixed bonus and a variable bonus linked to the performance of the Company and to his capacity to manage remuneration costs.

The management team members receive a fixed remuneration plus a variable bonus that is linked to their personal achievements (i.e. experience, know-how, education, skills, responsibilities, and performance) and the achievements of the Company. The remuneration is closely linked to performance. Bonuses, if any, are linked to identifiable objectives and to special projects and are set and measured on a calendar-year basis. Non-performers are not retained in the Company. The performance objectives of the management team members are primarily evaluated with regard to the following criteria: (i) respect of the Board-approved annual budget, and (ii) meeting measurable operational targets. The various objectives and their weighting may differ for the individual managers. The nomination and remuneration committee of the Board of Directors meets annually to review the performance of the managers, to compare the actual measurable results to the objectives that were pre-defined by the committee, and to establish the measurable objectives for the ensuing calendar year.

Each member of the executive management who is a salaried employee may be entitled to a number of fringe benefits, which may include participating in a defined contribution pension or retirement scheme, disability insurance, a company car, a mobile telephone, internet access and/or a laptop computer according to general Company policy, and other collective benefits (such as hospitalization insurance and meal vouchers).

In 2019, all the members of the executive management were engaged on the basis of an employment contract. The employment contracts are generally for an indefinite term, with a trial period. The employment contracts may be terminated at any time by the Company, subject to a severance notice or payment in line with market standards (see also above). The employment contracts include, where appropriate, non-competition undertakings, as well as confidentiality and IP transfer undertakings (that will try to seek maximum protection of the Company's interests, under applicable laws and subject to the employee's agreement).



Executive members who are engaged on the basis of a services contract do not receive fringe benefits, except that they may be provided with a mobile phone and laptop computer according to General Company policy, and they qualify for reimbursement of expenses incurred while carrying out their professional responsibilities.

Executive managers of the Company that are employed under employee contracts are entitled to enroll in defined-contribution type pension plans (such as 401K plans in the United States). The assets of these pension plans are held and managed by third-party organizations and the Company only makes contributions to these plans during the term of service of the employee. Executive managers of the Company that are engaged on the basis of a service agreement are not entitled to any pension plans or pension plan contributions from the Company.

## Subscription rights

Share options granted by the Company generally take the form of subscription rights in the sense of Article 496 and seq. of the Belgian Company Code and Article 7:67 and seq. Subscription rights can periodically be awarded to managers, Directors, employees, or even certain consultants, primarily as a retention and motivation tool. Subscription rights typically vest over time (subject to the beneficiary remaining with the Company) and can only be exercised after a specific period of time, except where the Company decides otherwise. There was no significant change in the remuneration policy in 2019.

## Expected changes with respect to accounting year 2020 and the following accounting year

Besides the setting in place of a cash only remuneration scheme for the Non-Executive Independent Directors, as aforementioned, no significant change to the remuneration policy of Directors and Executive managers is envisaged for 2020 or the following accounting year. However, the Company will continuously review the remuneration of Directors and Executive managers against market practice.

The bonuses of the management team members for 2020 and the following accounting year will be primarily linked to the following objectives:

- respect of the Board-approved annual budget, with a focus on revenue growth and cash-flow management;
- meeting measurable operational targets, including specific operational and commercialization goals.

Remuneration amounts for the reported year

## Remuneration earned by the Non-Executive Directors for the reported year

The following table provides the 2019 compensation of the Non-Executive Directors in function during 2019:

Name <sup>1</sup>	Position <sup>2</sup>	Pro-rata of annual retainer fee (€K)	Other services (€K)	Total <sup>3</sup> (€K)
Mr. Koen Hoffman	NED – Board Chair	35	0	35
Mr. Narajowski	NED – Chair NRC (until 30 Oct 2019)	23	0	23
Mr. Mariën	NED – member NRC	0	0	0
Mr. Pensaert	NED – member AC and NRC	0	0	0
Dr. Verplancke	NED – member AC and NRC	25	0	25
Ms. Windels	NED – Chair AC	30	0	30
Mr. Still	NED – Chair NRC (from 1 Nov 2019)	5	0	5

Notes:

<sup>1</sup>: Mr. Koen Hoffman serves on the Board as a permanent representative of Ahok BV.. Mr. Rudi Mariën serves on the Board as a permanent representative of Gengest BV. Mr. Jan Pensaert serves on the Board as a permanent representative of Valiance Advisors LLP. Dr. Lieve Verplancke serves on the Board as a permanent representative of Qaly-Co BV. Ms. Hilde Windels serves on the Board as a permanent representative of Hilde Windels BV. Mr. Tim Still serves on the Board as a permanent representative of TSTILL ENTERPRISES LLC. Mr. Walter Narajowski served on the Board as a permanent representative of LabDx, L.L.C until October 30, 2019.

<sup>2</sup>: “NED” = Non-Executive Director, “AC” = Audit Committee, “NRC” = Nomination & Remuneration Committee.

<sup>3</sup>: Excludes expense reimbursement and subscription rights. No other form of remuneration exists for Directors.

During the course of 2019, the composition of the Board of Directors changed. Notably, Mr. Walter Narajowski acting through LabDx, L.L.C resigned on October 30, 2019.

During the course of 2019, the Company has not deviated from its remuneration policy for the Non-Executive Directors. The total remuneration of the Board of Directors (including the Executive Director) in 2019 and 2018 was €432,000 (\$484,000) and €603,000 (\$713,000) respectively (excluding VAT, share-based compensation and expenses reimbursement).

On May 23, 2006, the Board of Directors decided, with application of Article 523 of the Belgian Company Code (Article 7:96 of the Belgian Companies and Associations Code), that the Company would indemnify the Directors against any claim by a third party based on Directors’ liability, except in the event of gross negligence and willful misconduct. Therefore, the Company has taken out Directors’ liability insurance.

The insurance policy was renewed in 2016. Additionally, the Company’s US subsidiary, MDxHealth, Inc., has entered into indemnification agreements directly with each of its Directors, as well as each Director of the Company, to indemnify each such person for liabilities to the extent that they may arise from, or claims therefor which are based on, US-associated activities of the US subsidiary or of the Company, including any claims based on a theory of derivative liability in the right of the US subsidiary.

## Remuneration earned by the Executive Director for the reported year

Dr. Jan Groen (who resigned as Director and CEO of the Company with effect as of February 18, 2019) was not remunerated for his position as an Executive Director of the Company in 2019.

## Remuneration earned by the CEO for the reported year

Mr. Michael K. McGarrity was hired as CEO starting on February 18, 2019. Mr. McGarrity is remunerated on the basis of his executive management position. As CEO, Mr. McGarrity is entitled to (a) a gross annual base salary of USD 400,000, which will be reviewed by the Board of Directors (or the Nomination and Remuneration Committee) on an annual basis, (b) an annual bonus of up to 50% of the then applicable base salary, (c) the grant of 1,500,000 share options, and (d) a one-time sign on bonus in the gross amount of USD 85,000. Furthermore, Mr. McGarrity is entitled to a reimbursement of expenses, and he and his dependents are eligible to participate in all group health, medical, dental, disability and insurance plans, incentive, savings and retirement plans, and other employee benefits that are established by the Company for its executives.

Excluding the value of subscription rights, the remuneration and benefits provided to the CEO in 2019 were composed as follows:

	<b>Euro (€)</b>	<b>\$ equivalent</b>
Fixed gross remuneration <sup>1</sup>	€309,204	\$346,153
Supplementary paid compensation <sup>2</sup> (gross)	€70,197	\$78,585
Pension benefits	€649	\$727
Other benefits <sup>3</sup>	€14,316	\$16,026
<b>Total</b>	<b>€394,366</b>	<b>\$441,491</b>

### Notes:

<sup>1</sup>: Total cost to the Company, including employer social security contributions and vacation pay accrual.

<sup>2</sup>: Excludes value of 1,500,000 subscription rights already created, issued, and accepted under the Company's 2017 Stock Option Plan.

<sup>3</sup>: Includes Company-paid and other similar benefits. Excludes reimbursement of normal professional expenses such as telephone and Company travel expenses.

In connection with being hired, the non-conflicted members of the Board of Directors agreed to grant Mr. McGarrity 1,500,000 new subscription rights (employee share options) in the Company, formally issued on May 5, 2019 under the Company's May 2017 Stock Option Plan. The subscription rights vest straight-line over 3 years, vesting shall occur over a three-year period, in three equal annual instalments on each anniversary of February 18, 2019, the date corresponding to Mr. McGarrity's date of hire. The exercise price of € 1.49 per warrant is based on the 30-day average market price prior to their issuance. The subscription rights are not exercisable until after the third anniversary of the date of their grant.

The Company's former CEO, Dr. Jan Groen, resigned as CEO and Director of the Company with effect as of February 18, 2019. For a temporary period following his resignation, Dr. Jan Groen served an advisor to the Company to provide limited advisory and related consulting services to the new CEO, Mr. McGarrity, in relation to the daily management of the Company. During 2019, he was remunerated on the basis of his executive management position. Excluding the value of subscription rights, the remuneration and benefits provided to the CEO in 2019 were composed as follows:

	<b>Euro (€)</b>	<b>\$ equivalent</b>
Fixed gross remuneration <sup>1</sup>	€628,797	\$703,938
Advisory and consulting <sup>2</sup>	€64,570	\$72,286
Other benefits <sup>3</sup>	€18,449	\$20,653
<b>Total</b>	<b>€711,816</b>	<b>\$796,877</b>

Notes:

<sup>1</sup>: Total cost to the Company, including employer social security contributions and vacation pay accrual.

<sup>2</sup>: Excludes value of 400,000 subscription rights already created, issued, and accepted (under several subscription rights plans).

<sup>3</sup>: Includes Company-paid housing, Company car, meal vouchers, and other similar benefits. Excludes reimbursement of normal professional expenses such as telephone and Company travel expenses.

During the course of 2019, the Company has not deviated from its remuneration policy for the Executive Director.

## Remuneration earned by other Executive Managers

The 2019 combined remuneration package of the other executive management team members in office in 2019 (excluding the CEO) - i.e. John Bellano, Ron Kalfus, Joseph Sollee and Jean-Marc Roelandt (and Kurt Schmidt) - including employer taxes, was €950,683

	<b>Euro (€)</b>	<b>\$ equivalent</b>
Fixed gross remuneration <sup>1</sup>	€805,356	\$901,596
Bonuses paid and awarded <sup>2</sup> (gross)	€64,512	\$72,221
Pension benefits	€26,148	\$29,273
Other benefits <sup>3</sup>	€54,666	\$61,199
<b>Total</b>	<b>€950,682</b>	<b>\$1,064,289</b>

Notes:

<sup>1</sup>: Includes employer taxes and vacation pay accrual. Excludes VAT.

<sup>2</sup>: Excludes value of subscription rights the Board of Directors has agreed to issue to certain other executive managers.

<sup>3</sup>: Includes for some individuals a Company car, meal vouchers, and other similar benefits. Excludes reimbursement of normal professional expenses such as telephone and Company travel expenses.

The total remuneration and benefits paid to the executive management team members (including the CEO) in 2019 and 2018 was €2,056,865 and €1,444,420 respectively (USD equivalent \$2,302,660 and \$1,705,560 respectively) (gross amount, excluding VAT and share based compensation). In the aforementioned figures, the service fees of the managers hired on the basis of a service agreement are included with the salaries of the other management team members.

The primary performance objectives for the bonuses of the above management team members in 2019 were the following:

- respect of the Board-approved annual budget, with a focus on cash-flow management
- meeting measurable operational targets, such as the commercialization of its ConfirmMDx for Prostate and SelectMDx for Prostate tests and attainment of revenue targets

In the course of 2019, no subscription rights were exercised by Directors and Executive managers.

During the course of 2019, the Company has not deviated from its remuneration policy for the executive managers.

## Special provisions of the contractual relationship of the Executive Managers

Each of the executive managers has a contractual employment agreement.

The Company hired Mr. Michael K. McGarrity, acting in the role of Chief Executive Officer, effective as of February 18, 2019. The executive employment agreement with Mr. McGarrity provides that if the Company terminates the employment agreement without cause or if Mr. McGarrity resigns for good reason, Mr. McGarrity shall be eligible to receive as severance an amount equal to twelve months of base salary in effect at the time of the separation.

Acting under the direction of Board, the Company hired Mr. Ron Kalfus, acting in the role of Chief Financial Officer, effective as of June 19, 2019. The employment agreement with Mr. Kalfus provides that if the Company terminates the employment agreement without cause or if Mr. Kalfus resigns for good reason, Mr. Kalfus shall be eligible to receive as severance an amount equal to six months of base salary in effect at the time of the separation, which amount will increase to twelve months of base salary for a termination that occurs after July 22, 2020.

Acting under the direction of Board, the Company hired Mr. John Bellano, acting in the role of Chief Commercial Officer, effective as of June 19, 2019. The employment agreement with Mr. Bellano provides that if the Company terminates the employment agreement without cause or if Mr. Bellano resigns for good reason, Mr. Bellano shall be eligible to receive as severance an amount equal to six months of base salary in effect at the time of the separation, which amount will increase to twelve months of base salary for a termination that occurs after June 19, 2020.

The employment contract with Mr. Sollee dates from before the entry into force of the law of April 6, 2010 on corporate governance in public and listed companies and is in conformity with common employment law. The contract with Mr. Sollee provides that if his employment is terminated for a reason other than serious misconduct or if Mr. Sollee resigns for good reason, he will be entitled to a severance pay of nine (9) months gross remuneration and benefits.

The contracts with the Executive managers and the Executive Director do not include a provision as referred to in Article 3:6, §3, al 2, 11° of the Belgian Companies and Associations Code: there is no contractual clause in the employment contracts or service agreements with the Executive Directors/management stating that the variable part of the remuneration based upon faulty financial information will be recovered by the Company.

## 2019 Share-based compensation of Directors and Executive Managers

During the course of 2019, the following share-based compensation was awarded to Directors and Executive managers of MDxHealth:

- Each Non-Executive Director serving on the Board as of May 29, 2019, the date of the 2019 annual general shareholders meeting, received 10,000 new warrants
- Michael McGarrity, CEO and Executive Director, received 1,500,000 new warrants
- The other members of the Executive management team received a total of 830,000 new warrants

Before the entry into force of the Belgian Companies and Associations Code, each Non-Executive Director (including Independent Directors) serving on the Board as of May 29, 2019, the date of the 2019 annual general shareholders meeting, received 10,000 new subscription rights with the following characteristics:

- Exercise price of €1.28 (one share option (subscription right) gives right to buy one share)
- Cliff vesting over 1 year for all beneficiaries
- Duration of options: 10 years

In reference to the 830,000 warrants granted to the other members of the Executive management team, all such warrants were granted on July 24, 2019 with the following characteristics:

- Exercise price of €1.24 (one stock option (warrant) gives right to buy one share)
- Straight-line vesting over 4 years for all beneficiaries
- Exercise Period: the warrants are not exercisable until after the third anniversary the date of their grant
- Duration of warrants: 10 years

The Company has not materially deviated from its remuneration policy during the financial reported year.

Done on April 23, 2020

On behalf of the Board of Directors

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# Part III: Principle Risks & Uncertainties

MDxHealth operates in a rapidly changing environment that involves a number of risks and uncertainties, some of which are beyond its control. This discussion highlights some of the principal risks and uncertainties, which may affect MDxHealth's business, financial condition and results of operation. The Company cannot be certain that it will successfully address these risks. Additional risks and uncertainties not presently known, which management currently deems immaterial or which are like those faced by other companies in the Company's industry or business in general, may also impair its business operations.

## Strategic and commercial risks

### **The molecular diagnostics industry is highly competitive and characterized by rapid technological changes**

The molecular diagnostics field is characterized by rapid technological changes, frequent new product introductions, changing customer preferences, emerging competition, evolving industry standards, reimbursement uncertainty and price competition. Moreover, the molecular diagnostics field is intensely competitive both in terms of service and price, and continues to undergo significant consolidation, permitting larger clinical laboratory service providers to increase cost efficiencies and service levels, resulting in more intense competition.

The market for assessing men at risk for prostate cancer is large. As a result, this market has attracted competitors, some of which possess substantially greater financial, selling, logistical and laboratory resources, more experience in dealing with third-party payors, and greater market penetration, purchasing power and marketing budgets, as well as more experience in providing diagnostic services. Some companies and institutions are developing serum-based tests and diagnostic tests based on the detection of proteins, nucleic acids or the presence of fragments of mutated genes in the blood that are associated with prostate cancer. These competitors could have technological, financial, reputational, and market access advantages over MDxHealth.

**The commercial success of MDxHealth will depend on the market acceptance and adoption of its tests**

Healthcare providers typically take a long time to adopt new products, testing practices and clinical treatments, partly because of perceived liability risks and the uncertainty of third-party coverage and reimbursement. It is critical to the success of the Company's sales efforts that it educates enough patients, clinicians and administrators about molecular diagnostics testing, in general, as well as about its tests, and demonstrate their clinical benefits. It is likely that clinicians may not adopt, and third-party payors may not cover or adequately reimburse for, the Company's tests unless they determine, based on published peer-reviewed journal articles and the experience of other clinicians, that they provide accurate, reliable and cost-effective information.

As the healthcare reimbursement system in the United States evolves to place greater emphasis on comparative effectiveness and outcomes data, MDxHealth cannot predict whether it will have sufficient data, or whether the data it has will be presented to the satisfaction of any payors seeking such data, in the process of determining and maintaining coverage for its diagnostic tests.

The administration of clinical and economic utility studies is expensive and demands significant attention from the management team. Data collected from these studies may not be positive or consistent with the Company's existing data, or may not be statistically significant or compelling to the medical community. If the results obtained from ongoing or future studies are inconsistent with certain results obtained from previous studies, adoption of diagnostic services would suffer and MDxHealth's business would be harmed.

If MDxHealth's tests or the technology underlying its current or future tests do not receive sufficient favorable exposure in peer-reviewed publications, the rate of clinician adoption of its tests and positive reimbursement coverage decisions for its tests could be negatively affected. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for diagnostic tests, and the Company's inability to control when, if ever, its results are published may delay or limit its ability to derive sufficient revenue from any product that is the subject of a study.

**MDxHealth's financial results are largely dependent on sales of one test, and it will need to generate sufficient revenues from this and other future solutions to grow its business.**

Revenues in 2019 were still largely dependent on the sales of the Company's ConfirmMDx test for Prostate Cancer. Revenues from sales of ConfirmMDx accounted for approximately 92% of products – and services revenues and is expected to decrease further over the next several years, based on anticipated sales of the SelectMDx for Prostate Cancer test. However, there can be no assurance that SelectMDx will be successfully commercialized. If the Company is unable to increase sales and reimbursement of ConfirmMDx or successfully develop and commercialize other solutions or enhancements, its revenues and its ability to achieve profitability would be impaired, and the market price of its shares could decline.

**MDxHealth's business could be materially harmed by the ongoing coronavirus (COVID-19) pandemic.**

Recently, an ongoing outbreak of a novel strain of coronavirus (COVID-19) has spread rapidly from China to many parts of the world. In March 2020, the World Health Organization declared the COVID-19 as a pandemic. The pandemic has resulted in quarantines, travel restrictions, and the temporary closure of stores and business facilities on a global scale for the past few months. Given the rapidly expanding nature of the COVID-19 pandemic, and because substantially all of our business operations and our workforce are concentrated in the US, which has recently reported significant COVID-19 related mortalities, we believe there is a substantial risk that our business, results of operations, and financial condition

may be adversely affected. Potential impact to our results of operations will also depend on future developments and new information that may emerge regarding the duration and severity of the COVID-19 pandemic and the actions taken by government authorities and other entities to contain the COVID-19 pandemic or mitigate its impact, almost all of which are beyond our control.

The impacts of COVID-19 on the Company's business, financial condition, and results of operations include, but are not limited to, the following:

- The Company temporarily implemented staggered laboratory shifts and work-from-home policies for non-essential personnel beginning in March 2020.
- The healthcare industry and our customers have been negatively impacted by the pandemic, shifting resources toward coronavirus care and limiting non-essential contact with patients, which is expected to delay and potentially reduce orders for the Company's testing solutions in 2020. As a result, MDxHealth revenue and income is expected to be negatively impacted.
- The situation may worsen if the COVID-19 pandemic continues or worsens, including for example from the diversion of healthcare resources and staff, delays or interruptions in clinical trial activities, interruption of, or delays in receiving, supplies of key laboratory testing components from contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, and limitations on employee resources because of sickness of employees or their families or the need for social distancing.
- The global stock markets have experienced, and may continue to experience, significant decline from the COVID-19 pandemic. It is possible that the price of the Company's shares may be negatively impacted.

#### **MDxHealth faces uncertainties over the reimbursement of its tests by third party payors**

Successful commercialization of the Company's tests depends, in large part, on the availability of coverage and adequate reimbursement from government and private payors. Favorable third-party payor coverage and reimbursement are essential to meeting the Company's immediate objectives and long-term commercial goals. The Company does not recognize revenue for test results delivered without a contract for reimbursement or without a history of consistent payment. In the US, for new diagnostic solutions, each private and government payor decides whether to cover the test, the amount it will reimburse for a covered test and the specific conditions for reimbursement. Clinicians and recipients may be likely not to order a diagnostic test unless third-party payors pay a substantial portion of the test price. Therefore, coverage determinations and reimbursement levels and conditions are critical to the commercial success of a diagnostic product.

Governmental payors, as well as private insurers, and other private payors have implemented and will continue to implement measures to control the cost, utilization and delivery of healthcare services, including laboratory services. US Congress has from time to time considered and implemented changes to laws and regulations governing healthcare service providers, including specialized diagnostic service providers. Additionally, with the recent implementation by the US Centers for Medicare and Medicaid (CMS) of a comprehensive oversight regime that consolidates program integrity powers into a single Unified Program Integrity Contractor (UPIC), audit and investigatory activity into potential billing fraud, waste and abuse in the industry has increased. These changes have adversely affected and may in the future adversely affect coverage and reimbursement for laboratory services, including the molecular diagnostics testing services MDxHealth provides.

Outside of the US, various coverage, pricing and reimbursement approvals are required. The Company expects that it will take several years to establish broad coverage and reimbursement for its tests with payors in countries outside of the US where it commercializes its solutions, and its efforts may not be successful. Even if public or private reimbursement is obtained, it may cover competing tests, the reimbursement may be conditioned upon local performance of the tests or other requirements MDxHealth may have difficulty satisfying. Reimbursement levels outside of the US may vary considerably from the reimbursement amounts the Company receives in the US. In addition, because MDxHealth plans in many circumstances to rely on distributors to obtain reimbursement for its tests, to the extent it does not have direct reimbursement arrangements with payors, the Company may not be able to retain reimbursement coverage in certain countries with a particular payor if its agreement with a distributor is terminated or expires or a distributor fails to pay for other reasons.

## Operational risks

### **If MDxHealth is unable to protect its intellectual property effectively, it may be unable to prevent third parties from using its intellectual property**

MDxHealth relies on patent protection as well as a combination of trademark, copyright and trade secret protection and other contractual restrictions to protect its proprietary technologies, all of which provide limited protection and may not adequately protect its rights or permit MDxHealth to gain or keep any competitive advantage. It is not certain that any of its currently pending or future patent applications will result in issued patents, or that any patents issued or licensed to the Company will not be challenged, invalidated or held unenforceable. Issued patents may not be broad enough to provide any meaningful protection. If MDxHealth fails to protect its intellectual property, third parties may be able to compete more effectively and the Company may incur substantial litigation costs in its attempts to recover or restrict use of its intellectual property.

### **MDxHealth is dependent on licenses and collaborations with third parties**

The Company licenses technology from third parties necessary to develop and commercialize its products. Termination of any of these licenses could prevent the Company from producing or selling some or all of its tests, and a failure of the licensors to abide by the terms of the licenses or to prevent infringement by third parties could harm the Company's business and negatively impact its market position.

MDxHealth is also engaged in several collaborations and licenses with commercial partners, such as leading pathology laboratories with large urology client bases. Failure to maintain these partnerships could adversely affect revenues and profitability.

### **MDxHealth faces an inherent risk of product liability claims**

The marketing, sale and use of MDxHealth's tests could lead to product or professional liability claims against it if someone were to allege that its tests failed to perform as they were designed, or if someone were to misinterpret test results or improperly rely on them for clinical decisions. Although MDxHealth maintains product and professional liability insurance which is deemed to be appropriate and adequate, it may not fully protect the Company from the financial impact of defending against product liability or professional liability claims or any judgments, fines or settlement costs arising out of any such claims. Furthermore, any product liability lawsuit could harm its reputation, which could impact its results of operations.



**Failure to attract or retain key personnel or to secure the support of key scientific collaborators could materially adversely impact MDxHealth's business**

Competition for desirable personnel is intense, and there can be no assurance that MDxHealth will be able to attract and retain the necessary staff. The failure to maintain management or to attract sales personnel as the Company moves towards the commercialization of its tests could materially adversely affect the business, financial condition and results of operations.

MDxHealth has established relationships with leading key opinion leaders and scientists at important research and academic institutions that it believes are key to establishing tests using its technologies as a standard of care for cancer assessment and diagnosis. If its collaborators determine that cancer testing using its technologies are not appropriate options for prostate cancer diagnosis, or superior to available prostate cancer methods, or that alternative technologies would be more effective in the early diagnosis of prostate cancer, the Company would encounter significant difficulty establishing tests using its technologies as a standard of care for prostate cancer diagnosis, which would limit its revenue growth and profitability.

**MDxHealth laboratory facilities may become inoperable**

MDxHealth currently perform all its testing in its laboratory facilities located in Irvine, California and Nijmegen, The Netherlands. The Company does not have redundant laboratory facilities in the US or in Europe. Its laboratory facilities could become inoperable due to circumstances beyond its control, which could adversely affect its business and operations. The facilities, the equipment MDxHealth uses to perform its tests and services and its other business process systems would be costly to replace and could require substantial time to repair or replace.

The facilities may be damaged or destroyed by natural or man-made disasters, including earthquakes, wildfires, floods, acts of terrorism or other criminal activities, infectious disease outbreaks and power outages, which may render it difficult or impossible for MDxHealth to perform its tests for some period.

The facilities may also be rendered inoperable because of regulatory sanction. In the US, MDxHealth is subject to federal and state laws and regulations regarding the operation of clinical laboratories. The US Federal Clinical Laboratory Improvement Amendments (CLIA) and laws of California and certain other states, impose certification requirements for clinical laboratories, and establish standards for quality assurance and quality control, among other things. Clinical laboratories are subject to inspection by regulators, and to sanctions for failing to comply with applicable requirements. Sanctions available under CLIA include prohibiting a laboratory from running tests, requiring a laboratory to implement a corrective plan, and imposing civil monetary penalties.

**MDxHealth relies on a limited number of suppliers for manufacture and supply of its laboratory instruments and materials**

Many of the consumable supplies and reagents used as raw materials in the Company's testing process are procured from a limited number of suppliers, some of which are sole-source. In addition, it relies on a limited number of suppliers, or in some cases a single supplier, for certain equipment with which it performs testing services. Because the actual production or manufacture of such critical equipment and materials cannot be ensured, MDxHealth may be subject to significant delays caused by interruption in production or manufacturing, which could adversely affect its business, results of operations and financial condition.



### **Failure in MDxHealth's information technology, telephony or other systems could significantly disrupt business operations**

Information technology and telephony systems are used extensively in virtually all aspects of the business, including laboratory testing, sales, billing, customer service, logistics and management of medical data. The Company's information technology, telephony and other systems, are vulnerable to damage and failure, computer viruses, natural disasters and physical or electronic break-ins. Despite the precautionary measures MDxHealth has taken to prevent breakdowns in its information technology and telephony systems, sustained or repeated system failures that interrupt its ability to process test orders, deliver test results or perform tests in a timely manner or that cause it to lose patient information could adversely affect its business, results of operations and financial condition.

### **Security breaches or loss of data may harm MDxHealth's reputation, expose it to liability and adversely affect its business**

MDxHealth faces four primary risks relative to protecting sensitive and critical personally identifiable information, intellectual property or other proprietary business information about its customers, payors, recipients and collaboration partners, including test results: loss of access risk, inappropriate disclosure or access risk, inappropriate modification risk, and the risk of being unable to identify and audit controls over the first three risks.

The secure processing, storage, maintenance and transmission of this critical information is vital to the Company's operations and business strategy, and it devotes significant resources to protecting such information. Although measures to protect sensitive information from unauthorized access or disclosure are taken, MDxHealth's information technology and infrastructure, and that of its third-party billing and collections provider, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions.

Security breaches, the loss or misappropriation of data, privacy violations or the failure to implement satisfactory remedial measures could disrupt operations and lead to loss of reputation, regulatory penalties and other material financial losses and adversely affect MDxHealth's business, prospects, results of operations and financial condition.

## **Regulatory risks**

### **Failure to comply with governmental payor regulations could result in MDxHealth being excluded from participation in Medicare, Medicaid or other governmental payor programs, which would adversely affect MDxHealth's business.**

Failure to comply with applicable Medicare, Medicaid and other governmental payor rules could result in exclusion from participation in one or more governmental payor programs, returning funds already paid, civil monetary penalties, criminal penalties and/or limitations on the operational function of its laboratories. If MDxHealth were unable to receive reimbursement under a governmental payor program, a material portion of its revenue would decline, which could adversely affect results of operations and financial condition.

### **MDxHealth conducts business in a heavily regulated industry, and changes in regulations or violations of regulations may, directly or indirectly, adversely affect its results of operations and financial condition and harm its business**

MDxHealth's business operations and activities are subject to a range of healthcare laws and regulations (at the local, national and federal levels), as well as investigatory and program integrity oversight by Medicare, Medicaid and other governmental payer program auditors. The clinical laboratory testing industry is highly regulated, and there can be no assurance that the regulatory environment in which the Company operates will not change significantly and adversely to it in the future. In addition, the commercialization of any of its tests as kits will subject the Company to additional healthcare laws and regulations governing diagnostics products.

While MDxHealth believes that it is currently in material compliance with applicable laws and regulations, a determination that it has violated these laws, or the public announcement that it is being investigated for possible violations of these laws, would adversely affect its business, prospects, results of operations and financial condition.

If its operations or products are found to be in violation of any applicable laws and regulations, MDxHealth may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of its operations, the exclusion from participation in governmental healthcare programs and imprisonment, any of which could adversely affect its business and results of operations. In addition, a significant change in any of these laws may require the Company to change its business model to maintain compliance with these laws, which could reduce revenue or increase costs and adversely affect its business, prospects, results of operations and financial condition.

**MDxHealth's operating results could be materially adversely affected by unanticipated changes in tax laws and regulations, adjustments to its tax provisions, exposure to additional tax liabilities, or forfeiture of its tax assets.**

MDxHealth is subject to laws and regulations on tax levies and other charges or contributions in different countries, including transfer pricing and tax regulations for the compensation of personnel and third parties. MDxHealth's tax structure involves several transfers and transfer price determinations between its parent company and its subsidiaries or other affiliates. The Company's effective tax rates could be adversely affected by changes in tax laws, treaties and regulations, both internationally and domestically. An increase of the effective tax rates could have an adverse effect on its business, financial position, results of operations and cash flows.

## Financial risks

**MDxHealth has a history of losses, and expects to incur net losses for the next several years**

MDxHealth has incurred substantial net losses since its inception, and there can be no assurance that it will achieve profitability. Even if the Company achieves significant revenues, it may not become profitable, and even if it achieves profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain consistently profitable could adversely affect the market price of MDxHealth's common stock and could significantly impair its ability to raise capital, expand its business or continue to pursue its growth strategy.

**MDxHealth might require substantial additional funding to respond to business challenges or take advantage of new business opportunities, which may not be available on acceptable terms, or at all**

At the end of 2019, cash and cash equivalents totaled \$22.1 million. Although the Company believes that it has sufficient

capital to fund its operations through 2020, capital outlays and operating expenditures are expected to increase over the next several years as commercial operations. MDxHealth may require additional equity or debt funding from time to time to respond to business challenges or take advantage of new business opportunities, which may not be available at acceptable terms, or at all.

If additional funds are raised through the sale of equity, convertible debt or other equity-linked securities, stockholders' ownership will be diluted. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of common stock. If additional funds are raised by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of common stock, and the terms of the debt securities issued could impose significant restrictions on the Company's operations.

If adequate funds are not available, MDxHealth may have to scale back its operations or limit its research and development activities, which may cause the Company to grow at a slower pace, or not at all, and the business could be adversely affected.

**MDxHealth may engage in acquisitions that could disrupt its business, cause dilution to its stockholders and reduce its financial resources.**

In addition to the acquisition of NovioGendix, a privately held company based in Nijmegen (The Netherlands), in September 2015, MDxHealth may enter into other transactions in the future to acquire other businesses, products or technologies. Any acquisitions may not strengthen the Company's competitive position, and these transactions may be viewed negatively by customers or investors.

The Company could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification it may obtain from the seller. In addition, MDxHealth may not be able to successfully integrate the acquired personnel, technologies and operations into its existing business in an effective, timely and non-disruptive.

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# Part IV: Financial Statements



## Part IV:

# Financial Statements

## Consolidated financial statements

The following consolidated accounts are prepared in accordance with International Financial Reporting Standards (IFRS) as adopted in the EU. The accounting policies and notes are an integral part of these consolidated financial statements. The following consolidated accounts differ from the non-consolidated statutory annual accounts of the Company, which have been prepared in accordance with Belgian GAAP.

The financial statements in this section of the Annual Report have been approved and authorized for issue by the Board of Directors at its meeting of April 23, 2020. The financial statements have been signed by Mr. Michael McGarrity, Executive Director, on behalf of the Board of Directors. The financial statements will be submitted to the shareholders for their final approval at the annual general shareholders' meeting of May 28, 2020.

## Consolidated statement of profit and loss

Thousands of \$ (except per share amounts) For the years ended December 31	Notes	2019	2018 <sup>2</sup>
Services	3	11,443	27,710
Licenses	3	250	512
Royalties	3	92	116
Government grants	3	0	59
<b>Revenues</b>		<b>11,785</b>	<b>28,397</b>
Cost of goods & services sold	3	-11,755	-11,652
<b>Gross profit</b>		<b>30</b>	<b>16,745</b>
Research and development expenses	4	-8,997	-4,280
General and administrative expenses	4	-15,196	-15,207
Selling and marketing expenses	4	-17,809	-29,591
Other operating income		1	261
Other operating expenses		-1,198	-26
<b>Operating Loss</b>		<b>-43,169</b>	<b>-32,098</b>
Financial income	6	10	21
Financial expenses	6	-516	-414
<b>Loss before income tax</b>		<b>-43,675</b>	<b>-32,491</b>
Income tax	7	575	41
<b>Loss for the year</b>		<b>-43,100</b>	<b>-32,450</b>
<b>Earnings per share attributable to parent (EPS)</b>			
<b>Basic and Diluted, \$</b>	19	<b>-0.69</b>	<b>-0.56</b>

<sup>2</sup> The comparative figures have been reclassified to reflect the breakdown of Selling, general and administrative expenses into General and administrative expenses and Selling and marketing expenses.

## Consolidated statement of comprehensive income

Thousands of \$ For the Years ended December 31	Notes	2019	2018
<b>Loss for the year</b>		<b>-43,100</b>	<b>-32,450</b>
<b>Other comprehensive income</b>			
Items that will be reclassified to profit or loss:			
Exchange differences arising on translation of foreign operations		253	-2,408
<b>Total comprehensive loss for the year (net of tax)</b>		<b>-42,847</b>	<b>-34,858</b>



## Consolidated statement of financial position

### Assets

Thousands of \$ For the years ended December 31	Notes	2019	2018*
<b>ASSETS</b>			
<b>Non-current assets</b>			
Goodwill	8	0	1,145
Intangible assets	9	7,269	14,394
Property, plant and equipment	10	1,067	2,013
Right-of-use assets	10	1,385	61
<b>Total non-current assets</b>		<b>9,721</b>	<b>17,613</b>
<b>Current assets</b>			
Inventories	11	1,192	1,807
Trade receivables	12/18	6,645	19,062
Prepaid expenses and other current assets	12	1,020	791
Cash and cash equivalents	13/18	22,050	26,203
<b>Total current assets</b>		<b>30,907</b>	<b>47,863</b>
<b>TOTAL ASSETS</b>		<b>40,628</b>	<b>65,476</b>

## Liabilities & Shareholders' Equity

Thousands of \$ For the years ended December 31	Notes	2019	2018*
<b>EQUITY</b>			
Share capital	21	62,841	53,877
Issuance premium	21	136,349	135,731
Retained earnings		-186,638	-143,538
Share-based compensation	23	8,090	7,218
Translation reserve		-918	-1,171
<b>Total equity</b>		<b>19,724</b>	<b>52,117</b>
<b>LIABILITIES</b>			
<b>Non-current liabilities</b>			
Loans and borrowings	14/18	9,052	0
Lease liabilities	14/15	735	262
Deferred tax liabilities	7	0	575
Other non-current financial liabilities	15/18	690	1,045
<b>Total non-current liabilities</b>		<b>10,477</b>	<b>1,882</b>
<b>Current liabilities</b>			
Loans and borrowings	14/18	565	147
Lease liabilities	14/15	650	117
Trade payables	17/18	4,958	6,453
Other current liabilities	17	3,345	4,358
Other current financial liabilities	15/18	909	402
<b>Total current liabilities</b>		<b>10,427</b>	<b>11,477</b>
<b>Total liabilities</b>		<b>20,904</b>	<b>13,359</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>40,628</b>	<b>65,476</b>

\* The comparative figures have been reclassified to reflect the breakdown of the right-of-use assets from the property, plant & equipment and the lease liabilities from the loans and borrowings.

## Consolidated statement of changes in equity

Thousands of \$	ATTRIBUTABLE TO OWNERS OF MDXHEALTH SA				
	Share capital & issuance premium	Retained earnings	Share-based compensa- tion	Translation reserve	Total equity
Notes	21		23		
<b>Balance at January 1, 2018</b>	<b>147,185</b>	<b>-111,088</b>	<b>6,212</b>	<b>1,237</b>	<b>43,546</b>
Loss for the year		-32,450			-32,450
Other comprehensive income				-2,408	-2,408
<b>Total comprehensive income for the year</b>		<b>-32,450</b>		<b>-2,408</b>	<b>-34,858</b>
<b>Transactions with owners in their capacity as owners:</b>					
Issuance of shares	44,311				44,311
Deduction of transaction costs	-1,888				-1,888
Share-based compensation costs			1,006		1,006
<b>Balance at December 31, 2018</b>	<b>189,608</b>	<b>-143,538</b>	<b>7,218</b>	<b>-1,171</b>	<b>52,117</b>
<b>Balance at January 1, 2019</b>	<b>189,608</b>	<b>-143,538</b>	<b>7,218</b>	<b>-1,171</b>	<b>52,117</b>
Loss for the year		-43,100			-43,100
Other comprehensive income				253	253
<b>Total comprehensive income for the year</b>		<b>-43,100</b>		<b>253</b>	<b>-42,847</b>
<b>Transactions with owners in their capacity as owners:</b>					
Issuance of shares	10,040				10,040
Deduction of transaction costs	-458				-458
Share-based compensation costs			872		872
<b>Balance at December 31, 2019</b>	<b>199,190</b>	<b>-186,638</b>	<b>8,090</b>	<b>-918</b>	<b>19,724</b>

## Consolidated statement of cash flow

Thousands of \$/ For the years ended December 31	Notes	2019	2018
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
<b>Operating loss</b>		<b>-43,169</b>	<b>-32,098</b>
Depreciation and amortization	9/10	3,420	2,937
Impairment	8/9	6,292	0
Share-based compensation	23	872	1,006
Other non-cash transactions		1	-97
<b>Cash used in operations before working capital changes</b>		<b>-32,584</b>	<b>-28,252</b>
Decrease in inventories	11	615	112
Decrease in receivables	12	12,188	717
Decrease in payables	17/18	-2,508	-1,120
<b>Net cash outflow from OPERATING ACTIVITIES</b>		<b>-22,289</b>	<b>-28,543</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Purchase of property, plant and equipment	10	-73	-433
Purchase of intangible assets	9	0	-912
<b>Net cash outflow from investing activities</b>		<b>-73</b>	<b>-1,345</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Proceeds from issuance of shares (net of transaction costs)	21	9,582	42,423
Proceeds from the issuance of long-term debt	14/15	10,111	0
Payment of long-term debt	15	-589	-190
Payment of lease liability	15	-815	-168
Payment of interest	6	-324	-393
<b>Net cash inflow from financing activities</b>		<b>17,965</b>	<b>41,672</b>
<b>Net (decrease)/increase in cash and cash equivalents</b>		<b>-4,397</b>	<b>11,784</b>
Cash and cash equivalents at beginning of the financial year		26,203	16,827
Effect on Exchange rate changes		244	-2,408
<b>Cash and cash equivalents at end of the financial year</b>	<b>13/18</b>	<b>22,050</b>	<b>26,203</b>

# Notes

## Notes to consolidated financial statements

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MDxHealth SA (“The Company”) is a limited liability company incorporated in Belgium.

MDxHealth is a molecular diagnostics company that develops and commercializes advanced epigenetic and other molecular tests for cancer assessment and the personalized treatment of patients. Applying its DNA methylation platform and proprietary biomarkers, the Company helps address a large and growing unmet medical need for better cancer diagnosis and treatment information. The Company develops and commercializes advanced molecular diagnostic products for personalized cancer treatment that provide physicians with tools to aid in the diagnosis and or prognosis of cancers, and aid in the physician’s ability to predict disease progression and response to therapy. MDxHealth’s products and pipeline cover primarily urologic cancers, but in addition, MDxHealth has numerous proprietary biomarkers for other solid cancer types ready for development.

MDxHealth’s assays deliver highly accurate analytical results and can be performed on a variety of sample types including formalin-fixed paraffin embedded (FFPE) tissue, fresh/frozen tissue, urine, plasma, serum, sputum, broncho-alveolar lavages and stool using commercially available PCR equipment.

MDxHealth offers our laboratory solutions from our state-of-the-art, 13,444 sqft, College of American Pathologists (CAP)-accredited and Clinical Laboratory Improvement Amendments of 1988 (“CLIA”)certified, molecular laboratory facility located at our U.S. headquarters in Irvine, California. MDxHealth also operates in The Netherlands where MDxHealth BV offers the design and development, manufacturing, service laboratory activities and client services of in vitro diagnostic test kits, in vitro diagnostic reagents used for molecular diagnostic detection of oncological diseases from our ISO 13485:2016 certified, molecular laboratory facility located at our headquarters in Nijmegen, the Netherlands.

The Company is headquartered in Belgium. The parent company, MDxHealth SA, has its registered and corporate office in Cap Business Center, Rue d’Abhooz 31, 4040 Herstal, Belgium. MDxHealth, Inc., the Company’s US subsidiary, is located at 15279 Alton Parkway – Suite 100 – Irvine, CA 92618, United States. MDxHealth B.V., the Company’s Dutch subsidiary, is located at Transistorweg 5, 6534 Nijmegen, The Netherlands.

The functional and presentation currency is the US Dollar.

**NOTE 2: Summary of Significant Accounting policies** [Back to Notes list](#)**2.1. Basis of preparation and statement of compliance**

MDxHealth’s consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS) and interpretations issues by the IFRS Interpretations Committee (IFRS IC) applicable to companies reported under IFRS. The financial statements comply with IFRS as issued by the International Accounting Standards Board (IASB) as adopted by the European Union.

The principal accounting policies applied in the preparation of the consolidated financial statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated. All amounts are presented in thousands of US Dollars (\$) unless otherwise indicated, rounded to the nearest thousand.



## 2.2. Basis of consolidation

The consolidated financial statements incorporate the financial statements of MDxHealth SA (Belgium), MDxHealth Inc. (United States), and MDxHealth BV (The Netherlands) for each fiscal year ending on December 31.

Subsidiaries are all entities over which the Company has control. The Company controls an entity when the Company is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Company. The acquisition method of accounting is used to account for business combinations by the Company.

All intercompany balances, profits and transactions are eliminated upon consolidation.

## 2.3. Going concern

The Company has experienced net losses and significant cash used in operating activities since its inception in 2003, and as of December 31, 2019, had an accumulated deficit of \$186.6 million, a net loss of \$43.1 million, and net cash used in operating activities of \$22.3 million. Management expects the Company to continue to incur net losses and have significant cash outflows for at least the next twelve months. While these conditions, among others, could raise substantial doubt about our ability to continue as a going concern, these consolidated financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the recovery of our assets and the satisfaction of liabilities in the normal course of business. A successful transition to attaining profitable operations is dependent upon achieving a level of positive cash flows adequate to support the Company's cost structure.

As at December 31, 2019, the Company had cash and cash equivalents of \$22.1 million. Following a comprehensive strategic evaluation in 2018, the company decided to increase the strategic focus on its two commercial products, ConfirmMDx and SelectMDx, delay certain product pipeline initiatives, and reduce overall operating spend. These measures have led to significant reductions in cash operating expenses in 2019. In addition, in April 2020, the Company entered into a subscription agreement with MVM V LP and MVM GP (No.5) LP, funds managed by MVM Partners LLP, to subscribe for 20,162,924 new shares for an aggregate subscription amount of €12.7 million, or approximately \$14 million (for further details of this transaction, refer to Note 26 Subsequent Events). The Company and its Board of Directors believe that, with its current cash position, along with the cash to be received from MVM Partners LLP upon closing of the transaction in May 2020, and taking into account management's expectation of the limited impact of the COVID-19 pandemic, will provide the Company with sufficient liquidity to continue its current operations at least until May 2021.

## 2.4. Use of estimates and judgments

Management makes certain critical accounting estimates and management judgment when applying the Company's accounting policies, which affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Estimates and judgments are continuously evaluated based on historical experience and other factors, including expectations of future events, which are believed to be reasonable under the circumstances. In the future, actual experience may differ from these estimates and assumptions.

The areas where assumptions and estimation uncertainties in the financial statements have potentially the most significant effect in 2019, are included in the following notes: Revenue Recognition (note 3); Deferred Income Tax (note 7); Right-of-Use Assets and Liabilities (notes 10 and 14), Impairment Testing (notes 8 and 9); Internally Generated Development Costs (note 9); Share-Based Payments (note 23); and Recognized Fair Value Measurements (notes 18 and 25).

Management has exercised judgments in the application of its accounting policies and those that have the most significant effect on the amounts recognized in the financial statements is the Company's ability to continue as a Going Concern (note 2.3) and revenue recognition (note 2.7).

## 2.5. New Standards, Interpretations and Amendments

### 2.5.1. New Standards, Interpretations and Amendments adopted by the Company

During the current financial year, the Company has adopted all the new and revised Standards and Interpretations issued by the International Accounting Standards Board (IASB) and the International Financial Reporting Interpretations Committee (IFRIC) of the IASB, that are relevant to its operations and effective for the accounting year starting on January 1, 2019. The Company has not applied any new IFRS requirements that are not yet effective as per December 31, 2019.

- IFRIC 23 Uncertainty over income tax treatments

Uncertainty over income tax treatments has been applied as from 1 January 2019. The adoption of this new interpretation did not have an impact.

- IFRS 16 Leases

The Company has applied IFRS 16 as from January 1, 2019, by using the modified retrospective approach, not restating comparatives for the 2018 reporting period. The reclassifications and the adjustments arising from the new leasing standard are recognized in the opening balance sheet on January 1, 2019.

On the adoption of IFRS 16, the Company recognized lease liabilities in relation to leases which had previously been classified as "operating leases" under the IAS 17 Leasing standard. These leases were measured at the present value of the remaining lease payments, using a discount rate based on the incremental borrowing rate as of January 1, 2019. The weighted average discount rate applied to the lease liabilities at January 1, 2019 was 3.72%.

The Company had leases classified as finance leases under IAS 17 for an amount of \$403,000 net book value for which the carrying amount has not been reassessed consistent with the transition requirements when using the modified retrospective approach.

The table below shows the reconciliation of the IAS 17 operating lease commitments disclosed in the 2018 consolidated financial statements with the IFRS 16 right-of-use asset at January 1, 2019:

In thousands of \$	As at January 1, 2019
Non-cancellable operating lease commitments disclosed as at December 31, 2018	2,265
Discounted using the company's incremental borrowing rate	-257
Add: finance lease liabilities recognized at December 31, 2018	379
(Less) short-term lease recognized on a straight-line basis as an expense	-7
(Less) low-value leases recognized on a straight-line basis as an expense	-56
Add/(Less) adjustments related to different treatment extension and termination options	-212
<b>Lease liability recognized as at January 1, 2019</b>	<b>2,112</b>

The right-of-use assets for all assets were measured at the amount equal to the lease liability and relate to the following assets (excluding existing finance leases):

In thousands of \$	As at December 31, 2019	As at January 1, 2019
Buildings	1,000	1,570
Vehicles	81	138
Materials	20	25
<b>Total right-of-use assets</b>	<b>1,101</b>	<b>1,733</b>
<b>Total lease liabilities</b>	<b>1,135</b>	<b>1,733</b>

The impact on the consolidated statement of profit and loss for the year ended December 31, 2019 and the basic and diluted loss per share is not significant. There was no impact on the retained earnings as per January 1, 2019. The 2018 comparatives were however changed to reclass the finance leases from the line property, plant and equipment to right-of-use assets and the lease liabilities from loans & borrowings to the line lease liabilities.

In applying IFRS 16 at January 1, 2019, the company has used the following practical expedients permitted by the standard:

- The use of a single discount rate to a portfolio of leases with similar characteristics;
- The accounting for operating leases with a remaining lease term of less than 12 months as at 1 January 2019 as short-term leases;
- The accounting for operating leases with a low value (less or equal to \$5,000) as low-value leases; and
- The use of hindsight in determining the lease term where the contract contains options to extend or terminate the lease.

The other new standards and interpretations effective as of January 1, 2019 did not have any impact on the statement of financial position and the statement of profit and loss.

#### 2.5.2. Standards and Interpretations issued but not yet effective in the current period

The Company elected not to early adopt the following new Standards, Interpretations and Amendments, relevant for the Company and which have been issued by the IASB and the IFRS IC but are not yet effective as per December 31, 2019 and/or not yet adopted by the European Union as per December 31, 2019 and for which the impact might be relevant.

- Amendments to IAS 1 and IAS 8 Definition of Material (applicable for annual periods beginning on or after 1 January 2020)
- Amendments to IFRS 9, IAS 39 and IFRS 7 Interest Rate Benchmark Reform (applicable for annual periods beginning on or after 1 January 2020, but not yet endorsed in the EU)
- Amendments to references to the Conceptual Framework in IFRS standards (applicable for annual periods beginning on or after 1 January 2020, but not yet endorsed in the EU)

## 2.6. Foreign currency translation

### Functional and presentation currency

Items included in the financial statements of each of the Company's entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The Company's functional and presentation currency is the US dollar based on the continuing development of the commercial activities in the US market.

Foreign currency transactions are translated into the functional currency using the exchange rates at the date of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year end exchange rates are generally recognized in profit or loss.

The results and financial positions of foreign operations that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- Assets and liabilities for each balance sheet presented are translated at the closing rate at the date of that balance sheet
- Income and expenses for each statement of profit or loss and statement of comprehensive income are translated at average exchange rates, and
- All resulting exchange differences are recognized in other comprehensive income.

## 2.7. Revenue recognition

### Performance obligations and timing of revenue recognition

The majority of the Company's revenue is derived from laboratory services with revenue recognized at a point in time when control of the services has transferred to the customer. This is generally when the test results are delivered to the customer.

Minor other Company's revenue is derived from license fees, royalties and government grants:

- License fees are recognized when the Company has fulfilled all conditions and obligations. If the Company has continuing performance obligations towards the fees, the fee will be recognized on a straight-line basis over the contractual performance period.

- Royalties are recognized as revenue once the amounts due can be reliably estimated based on the sale of the underlying products and services and when the collection of the royalties can be reasonably assured.
- Government grants are recognized as revenue over the life of the grant as the required or planned activities are performed and the related costs incurred and when there is reasonable assurance that the Company will comply with the conditions of the grant.

License fees are recognized when the Company has fulfilled all conditions and obligations. A license fee will not be recognized if the amount cannot be reasonably estimated and if the payment is doubtful.

License up-front (signature fees) and non-refundable fees for access to prior research results and databases are recognized when earned, if the Company has no continuing performance obligations and all conditions and obligations are fulfilled. If the Company has continuing performance obligations towards the fees, the fee will be recognized on a straight-line basis over the contractual performance period.

Royalties are generated from the sales by third parties of products or services which incorporate the Company's proprietary technology. Royalties are recognized as revenue once the amounts due can be reliably estimated based on the sale of the underlying products and services and when the collection of the royalties can be reasonably assured.

## Determining the transaction price

A large portion of the Company's revenues are derived from Medicare, which has set a fixed price (via a Local Coverage Determination or "LCD") for the Company's ConfirmMDx test. Therefore, the amount of revenue recognized from Medicare for ConfirmMDx is determined by reference to the fixed price in the LCD.

For other commercial insurance companies for ConfirmMDx and SelectMDx, where there is no certainty of the amount that will be paid for services rendered, the Company uses historical collection data – on an individual payor basis – to estimate its future collection and corresponding revenues that should be recognized for each of ConfirmMDx and SelectMDx.

The Company analyzes historical collection data on a quarterly basis and makes quarterly adjustments to its estimates. In accordance with IFRS 15, revenue is recognized where such a variable consideration is included in the transaction price only to the extent that it is highly probable that the amount of revenue recognized will not be subject to significant future reversals as a result of subsequent re-estimation.

When historical collection data is insufficient to estimate future collections, the Company defaults to cash basis, meaning that revenues will not be recognized until actual cash payment is received from the payor.

Total revenue in any given year includes amounts related to tests performed in previous years as:

- unrecognized amounts are collected;
- recognized amounts are collected for different amounts than initially accrued for; and
- balances outstanding for more than 12 months are not reversed.

## Costs of obtaining long-term contracts and costs of fulfilling contracts

The Company has no contracts of periods longer than one year. Consequently, no costs of obtaining long-term contracts nor assets for work in progress are recognized.

## 2.8. Segment information

Information for the Company's operating segments has been determined by reference to the information used by the chief operating decision maker [CODM] of the Company to review the performance of the Company and in making decisions on allocation of resources, the nature of the activities and the management structure and accountabilities. The Company's CEO has been identified as the chief operating decision maker in accordance with his designated responsibility for the allocation of resources to operating segments and assessing their performance through periodic reporting. The CODM periodically reviews the Company's performance based on information at a company level.

The Company does not distinguish different business segments since most revenues are generated from clinical laboratory service testing, or the out-licensing of the Company's patented DNA methylation platform and biomarkers. On an ancillary and opportunistic basis, the Company may engage in contracting out its R&D and scientific expertise to commercial and non-commercial entities. The Company is not organized, nor does it operate along business lines and all functions supported all the Company's commercial endeavors.

## 2.9. Goodwill

Goodwill represents the excess between the fair value of the consideration paid for an acquisition and the fair value of the Company's share of the net identifiable assets of the acquired company at the date of the acquisition. Where intangible assets are identified in the acquired company, such as intellectual property, brands, ongoing contracts or customer lists, these are valued to form part of the net identifiable assets.

Goodwill is not amortized but is tested for impairment annually, or more frequently if events or changes in circumstances indicate that it might be impaired and is carried at cost less accumulated impairment losses. Impairment of goodwill is not reversed.

Goodwill is allocated to cash generating units, which are expected to receive future economic benefits from synergies that are most likely to arise from the acquisition. These cash generating units form the basis of any future assessment of impairment of the carrying value of the goodwill.

## 2.10. Externally acquired intangible assets

Intangible assets are recognized on business combinations if they are separable from the acquired entity or give rise to other contractual/legal rights. The amounts ascribed to such intangibles are determined using appropriate valuation techniques.

Externally acquired patents and software licenses are initially recognized at cost and are subsequently amortized on a straight-line basis over their estimated useful lives on the following basis:

- Patents: shorter of 5 years or the remaining patent life
- Software: shorter of 5 years or the software license period
- Developed technology: 10 years
- In-Process Research and Development: indefinite until the completion or abandonment of the associated research and development effort.



## 2.11. Internally generated intangible assets (development costs)

Development costs are capitalized if it can be demonstrated that:

- It is technically feasible to develop the product for it to be sold;
- Adequate resources are available to complete the development;
- There is an intention to complete and sell the product;
- The Company is able to sell the product
- Sale of the product will generate future economic benefits, and;
- Expenditures on the project can be measured reliably.

Internally generated intangible assets are carried at their cost less any accumulated amortization and any accumulated impairment losses. Amortization over the asset's useful life shall begin when the asset is available for use.

## 2.12. Property, plant and equipment

Property, plant and equipment are stated at historical cost less accumulated depreciation and impairment. Repair and maintenance costs are charged to the income statement as incurred. Gains and losses on the disposal of property, plant and equipment are included in other income or expenses. Depreciation is charged to write off the cost or valuation of assets over their useful lives, using the straight-line method, on the following basis:

- Equipment: 5 years
- IT hardware and software: 3 years
- Furniture: 5 years
- Vehicles: 5 years
- Leasehold improvements: in line with the lease agreement period

## 2.13. Right-of-use assets and liabilities

Until 31 December 2018, leases of property, plant and equipment where the group, as lessee, had substantially all the risks and rewards of ownership were classified as finance leases. Finance leases were capitalized at the lease's inception at the fair value of the leased property or, if lower, the present value of the minimum lease payments. The corresponding rental obligations, net of finance charges, were included in non-current and current lease liabilities. Each lease payment was allocated between the liability and finance cost. The finance cost was charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period. The property, plant and equipment acquired under finance leases was depreciated over the asset's useful life, or over the shorter of the asset's useful life and the lease term if there is no reasonable certainty that the group will obtain ownership at the end of the lease term. Leases in which a significant portion of the risks and rewards of ownership were not transferred to the group as lessee were classified as operating leases. Payments made under operating leases (net of any incentives received from the lessor) were charged to profit or loss on a straight-line basis over the period of the lease.

### Right-of-use assets:

The Company recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date

less any lease incentives received. Unless the Company is reasonably certain to obtain ownership of the leased asset at the end of the lease term, the recognized right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life (see 2.12) and the lease term. Right-of-use assets are subject to impairment.

### **Lease liabilities:**

At the commencement date of the lease, the Company recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Company and payments of penalties for terminating a lease, if the lease term reflects the Company exercising the option to terminate. The variable lease payments that do not depend on an index or a rate are recognized as expense in the period on which the event or condition that triggers the payment occurs. In calculating the present value of lease payments, the Company uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the in-substance fixed lease payments or a change in the assessment to purchase the underlying asset.

### **Short-term leases and leases of low-value assets:**

The Company applies the short-term lease recognition exemption to its short-term leases of machinery and equipment (i.e., those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the lease of low-value assets recognition exemption to leases of office equipment that are considered of low value (i.e., below \$5,000). Lease payments on short-term leases and low-value assets are recognized in the consolidated statement of profit or loss as incurred.

## **2.14. Impairment of assets**

Goodwill acquired in a business combination and intangible assets that have an indefinite useful life are not subject to amortizations and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. Other assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or groups of assets (cash generating units). Non-financial assets other than goodwill that suffered an impairment are reviewed for possible reversal of the impairment at the end of each reporting period.

## **2.15. Inventories**

Inventories are initially recognized at cost, and subsequently at the lower of cost and net realizable value. Cost comprises merely purchase costs, as the inventory consists solely of raw materials. Raw materials are not ordinarily interchangeable and they are as such accounted for using the specific identification of their individual cost.

The Company does not account for work in progress and finished products.

## 2.16. Trade receivables

Trade receivables do not carry any interest and are recognized initially at fair value and subsequently measured at amortized cost, less provision for impairment.

## 2.17. Government Grants

A government grant is only recorded as a payable/receivable when (i) the grant has been approved by the granting party, (ii) the amounts are measurable, and (iii) the Company believes it will meet the conditions necessary to be able to receive/use the grant. This note is to be read together with the note related to Revenue recognition.

## 2.18. Cash and cash equivalents

Cash and cash equivalents are carried in the balance sheet at nominal value. For the purposes of the cash flow statements, cash and cash equivalents comprise cash on hand, deposits held on call with banks, other short-term highly liquid investments and bank overdrafts. Bank overdrafts, if any, are included in borrowings included in current liabilities.

## 2.19. Taxation

Current tax assets and liabilities for the current period are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted, at the reporting date.

Deferred income tax is provided in full using the “balance sheet liability method”, on temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes.

Deferred tax liabilities are recognized for all taxable differences. Deferred tax assets are recognized for all deductible temporary differences, carry forward of unused tax credits and unused tax losses, to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carry forward of unused tax credits and unused tax losses can be utilized.

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilized. Unrecognized deferred tax assets are reassessed at each reporting date and are recognized to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when the asset is realized or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Deferred tax assets and deferred tax liabilities are offset, if a legally enforceable right exists to set off current tax assets against current income tax liabilities and the deferred taxes relate to the same taxable entity and the same taxation authority.

## 2.20. Equity

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

## 2.21. Financial Assets

The financial assets consist mainly of trade receivables and other current assets (deposits).

### 2.21.1 *Classification and measurement on initial recognition*

The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Company's business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Company has applied the practical expedient, the Company initially measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component or for which the Company has applied the practical expedient are measured at the transaction price.

### 2.21.2 *Subsequent measurement*

After initial recognition, trade receivables and some other current assets are measured at amortised cost using the effective interest method, less provision for impairment based on expected credit losses.

### 2.21.3 *Impairment*

The Company recognizes an allowance for expected credit losses (ECLs) for all debt instruments not held at fair value through profit or loss. For trade receivables and contract assets, the Company applies a simplified approach in calculating ECLs. A loss allowance is recognized at each reporting date based on lifetime ECLs. The Company established a provision matrix that is based on its historical loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

For all other receivables, ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Company expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms. ECLs are recognized in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12-months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

## 2.22. Financial Liabilities

The financial liabilities consist mainly of loans and borrowings, lease liabilities, trade and other payables and contingent consideration related to business combinations.

### 2.22.1 *Measurement on initial recognition*

At initial recognition financial liabilities are measured at fair value minus transaction costs unless the financial liability is carried at fair value through profit or loss, in which case the transaction costs are immediately recognized in profit or loss. The best estimate of the fair value at initial recognition is usually the transaction price, represented by the fair value of the consideration given or received in exchange for the financial instrument. Any difference between the fair value estimated by the entity and the transaction price ("day one gain or loss") is recognized:

- in the income statement if the estimate is evidenced by a quoted price in an active market; and
- deferred as an adjustment to the carrying amount of the financial instrument in all other cases.

The fair value of the contingent consideration payable at the date of acquisition is computed as the sum of the probability weighted values of the fair values of the purchase prices associated with each of the potential product development routes. The fair value of each route is in turn computed as the sum of the survival probability discounted present values of the contingent payments in each such route including the milestone and commercialization payments. Any other financial liability included in the consideration payable for a business combination is recorded at fair value at the date of acquisition.

### 2.22.2 *Subsequent measurement*

After initial recognition, loans & borrowings, lease liabilities, trade and other payables, are measured at amortized cost using the effective interest method. The contingent consideration is measured at fair value and reviewed on a regular basis, and at least at each reporting date, and any changes in fair value are recorded in the consolidated statement of profit and loss.

## 2.23. Retirement benefit schemes and employee savings schemes

Payments to defined contribution employee savings schemes are charged as an expense as they fall due. The Company does not offer nor operate any defined benefit schemes for its employees.

## 2.24. Share-based compensation plans for personnel, directors and business associates

The Company grants stock options in accordance with several share-based compensation plans in consideration for services performed by personnel, directors and business associates. The cost of the services rendered is measured at the fair value of the granted options and recognized as an expense in the income statement. The corresponding credit is recorded directly into equity.

The estimate of the number of options which will ultimately vest is revised at each reporting date. The change in estimate is recorded as an expense with a corresponding correction in equity.

The received amount, less directly attributable transaction costs, will be recorded as share capital and share premium when the options are exercised.





**NOTE 3: Revenue and Cost of goods & services sold** [Back to Notes list](#)**Revenues**

Thousands of \$ For the years ended December 31	2019	2018
Services	11,453	27,710
Licenses	250	512
Royalties	92	116
Government grants	0	59
<b>Total revenue</b>	<b>11,785</b>	<b>28,397</b>

Total revenue for the year ended December 31, 2019 has decreased to \$11,785,000, compared to \$28,397,000 a year earlier. During the fourth quarter of 2019, and based on recent and historical collections data, the Company updated certain assumptions to its estimates which affected revenues:

- A revision of the period that a vast majority of collections would occur;
- An updated lookback period for historical collection experience in order to use more recent and relevant collection data;
- Recognition on cash basis if no historical payment experience is available.

Updating the revenue recognition estimates negatively affected its revenues for 2019 by \$10,078,000.

ConfirmMDx accounted for 92% of total services revenue in 2019 and 87% in 2018.

At the end of 2019, the Company had concluded agreements with 90 payors for ConfirmMDx (2018: 80) and 32 payors for SelectMDx (2018: 26). In 2018 Medicare established a Final Positive Local Coverage Determination for use of ConfirmMDx for Prostate Cancer.

**Segment revenue**

The Company does not distinguish different business segments since most revenues are generated from clinical laboratory service testing, or the out-licensing of the Company's patented DNA methylation platform and biomarkers. However, the Company does distinguish different geographical operating segments based on revenue since the revenues are generated both in United States of America and Europe.

In 2019, the Company earned 100% (2018: 99.8%) of its revenue from external customers from its clinical laboratory testing services and out-licensing of intellectual property. In 2019, the clinical laboratory testing in the US CLIA laboratory represented 89% of the Company's revenue (2018: 91%), while the out-licensing of intellectual property revenue and grant income in Europe represented 3% (2018: 9%).

In 2019, Medicare represented the only customer generating over 10% of the Company's revenues. In 2018, there were no customers responsible for the same condition.

The amount of its revenue from external customers broken down by location from the customers is shown in the table below:

Thousands of \$ For the years ended December 31	2019	2018
United States of America	10,878	27,798
The Netherlands	339	251
Belgium	32	85
Spain	194	60
Poland	38	57
Italy	43	49
Rest of EU	197	56
Rest of the world	64	41
<b>Total segment revenue</b>	<b>11,785</b>	<b>28,397</b>

At the end of 2019, 52% of the non-current assets were located in the US (2018: 45%) and the remaining 48% in Europe (2018: 55%).

## Contract assets and liabilities

The contract assets consist only of trade receivables. The Company does not have contract liabilities.

## Cost of goods & services sold

Thousands of \$ For the years ended December 31	2019	2018
Cost of goods & services sold	11,755	11,652
<b>Total cost of goods &amp; services sold</b>	<b>11,755</b>	<b>11,652</b>

The costs of goods include the costs associated with providing testing services to third parties.

NOTE 4: Nature of expenses [Back to Notes list](#)

## Research and development expenses

Thousands of \$/ For the years ended December 31	Notes	2019	2018
Personnel costs	5	1,143	1,293
Depreciation and amortization	9/10	1,283	1,177
Impairment	9	5,147	0
Lab consumables		480	726
External research and development collaborator fees		880	927
Other expenses		64	157
<b>Total research and development expenses</b>		<b>8,997</b>	<b>4,280</b>

Development expenses amounting to \$802,000 associated with the improvement of ConfirmMDx and SelectMDx were capitalized and included in intangible assets in 2018. No development expenses were capitalized during 2019. During 2019, the Company recorded an impairment loss on some of its intangible assets related to previously acquired IP (note 9).

## General and administrative expenses

Thousands of \$/ For the years ended December 31	Notes	2019	2018
Personnel costs	5	8,465	8,884
Depreciation and amortization	9/10	1,575	1,119
Professional fees		2,538	1,631
Travel expenses		124	218
Offices & facilities expenses		537	1,753
Royalties to third parties		174	333
Patent expenses		890	603
Board fees & expenses		170	177
Other expenses		723	489
<b>Total general and administrative expenses</b>		<b>15,196</b>	<b>15,207</b>

General and administrative expenses mainly represent general management costs, revenue cycle management, human resources, information technology, legal, finance, consulting, office and building costs. Professional fees increase is exclusively due to additional consulting services in the Company's US-based facilities. The adoption of IFRS 16 has transferred expenses from "Office & facilities" to "Depreciation"; the reclassification in 2019 is \$686,000.

## Selling and marketing expenses

Thousands of \$/ For the years ended December 31	Notes	2019	2018
Personnel costs	5	12,125	18,829
Depreciation	9/10	562	551
Professional fees		255	921
Marketing expenses		2,664	5,210
Travel expenses		837	1,293
Offices & facilities expenses		439	625
Clinical validation		546	2,033
Other expenses		381	129
<b>Total selling and marketing expenses</b>		<b>17,809</b>	<b>29,591</b>

During 2019, selling and marketing expenses decreased significantly after the strengthening and refocus of the Company's commercial organization.

### NOTE 5: Personnel costs [Back to Notes list](#)

Thousands of \$/ For the years ended December 31	2019	2018
The number of employees at the end of the year was:		
Management (headcount)	5	4
Laboratory staff (headcount)	12	13
S&M staff (headcount)	110	118
G&A staff (headcount)	51	52
Total	177	187
<b>Their aggregate remuneration comprised:</b>		
Wages and salaries	16,343	22,554
Social security costs	1,411	1,728
Pension costs	638	827
Health insurance expenses	1,882	2,336
Share-based compensation	872	1,006
Other costs	587	620
<b>Total personnel costs</b>	<b>21,733</b>	<b>29,071</b>

The personnel numbers in the table reflect year-end numbers. The operational plan announced by the Company on January 14, 2019 has led to a decrease in the number of employees and in total cost for employment.

**NOTE 6: Finance income / (expenses)** [Back to Notes list](#)

Thousands of \$/ For the years ended December 31	2019	2018
Interests income	10	21
Interests on bank loans	-318	-82
Foreign exchange loss	-4	-1
Other financial loss	-194	-331
<b>Net financial results</b>	<b>-506</b>	<b>-393</b>

During the fourth quarter of 2019, the Company entered into a loan facility with Kreos Capital in the amount of €9 million, or approximately \$10 million. The loan term is four years with the first 12 months of interest-only payments followed by 36 months of principal and interest payments. The financial results largely related to the interest charges paid for the loan facility with Kreos Capital for a total of \$194,000. Additionally, the Company recorded \$88,000 under interest charges on leases with the adoption of IFRS 16. Finally, the revaluation of the contingent consideration related to the acquisition of NovioGendix in 2015 represents a total of \$104,000 in 2019, and \$113,000 in 2018. Other financial losses relate to bank costs incurred during the year.

**NOTE 7: Taxes** [Back to Notes list](#)**Current income tax**

No income taxes were payable in view of the losses incurred by the Company. On December 31, 2019 the Company had a net tax loss carried forward amounting to \$371,179,000 (2018: \$214,280,000), implying a potential deferred tax asset of \$109,795,000 (respectively \$63,384,000 in 2018). The tax losses related to MDxHealth SA in Belgium are available for carry forward indefinitely.

The Company has a notional interest deduction to offset future taxable profits amounting to \$0 in 2019 and \$157,000 in 2018.

Tax credits amounted to \$422,000 in 2019 and \$450,000 in 2018.

It is uncertain if the Company will have taxable profits in the near future to allow all or part of the deferred tax asset to be utilized and as a result, no deferred tax asset was recognized in 2019 and 2018. The tax reconciliation and the impact of the unrecognized deferred tax assets is as follows:

	<b>Income Statement</b>	
Thousands of \$/ For the years ended December 31	2019	2018
Loss for the year	-43,100	-32,450
Income tax expense	-	-
Loss before income tax	-43,100	-32,450
Tax using the MDxHealth's domestic tax rate (29,58 % in 2019 and 29,58% in 2018)	-12,749	-9,599
Effect of unused tax losses not recognized as deferred tax assets	-12,749	-9,599

Deferred tax liabilities	In the consolidated statement of financial position		In the consolidated income statement	
	2019	2018	2019	2018
Thousands of \$/ For the years ended December 31				
Developed Technology	0	219	219	41
In-process research and development	0	356	356	-
<b>Total deferred tax liabilities</b>	<b>0</b>	<b>575</b>	<b>575</b>	<b>41</b>

The deferred tax liabilities relate to the intangible assets acquired and recognized as part of the business combination with MDXHealth BV (former NovioGendix). The entity also has tax losses carried forward for a total amount of \$12.1 million for which no deferred tax asset has been recognized.

Significant management judgment is required to determine the amount of deferred tax assets that can be recognized, based upon the likely timing and the level of future taxable profits together with future tax planning strategies. If the Company would recognize a deferred tax asset for the tax loss carryforward at December 31, 2019, the deferred tax assets would amount to \$12.1 million.

In relation with the impairment of the entire amount of the goodwill, together with the impairment of the In-process R&D, the management has decided to write-off the remaining amount of the deferred tax liability of \$575,000 during 2019.

#### NOTE 8: Goodwill [Back to Notes list](#)

The Company tests whether goodwill has suffered any impairment on an annual basis. The recoverable amount of the cash generating unit (CGU) including the goodwill is determined based on the fair value calculations by reference to the market value of the company as reflected by the quoted prices of its publicly listed shares.

Goodwill is not amortized but is tested for impairment annually, or more frequently if events or changes in circumstances indicate that it might be impaired and is carried at cost less accumulated impairment losses. Impairment of goodwill is not reversed.

The goodwill resulted from the allocation of the purchase price paid for the acquisition of MDxHealth BV in September 2015 and amounted to \$1,145,000. Since most revenues are generated from clinical laboratory service testing, the Company being the sole CGU, the annual impairment test was performed based on the recoverable amount of the entire Company. During the Company's annual impairment testing, the Company concluded that the recoverable amount of goodwill was zero and subsequently impaired the full amount of goodwill of \$1,145,000. The impairment charge has been presented in the line other operating expenses.



NOTE 9: Intangible assets [Back to Notes list](#)

Thousands of \$	Intellectual and property rights & Software licenses	Internally developed intangible assets	Externally acquired Developed Technology	Externally developed In-Process R&D	Total
<b>Gross value</b>					
<b>At January 1, 2018</b>	<b>5,011</b>	<b>8,531</b>	<b>4,500</b>	<b>3,300</b>	<b>21,342</b>
Additions— externally acquired	118				118
Additions— internally developed		802			802
Currency translation adjustments		-8			-8
<b>Gross value at December 31, 2018</b>	<b>5,129</b>	<b>9,325</b>	<b>4,500</b>	<b>3,300</b>	<b>22,254</b>
<b>Accumulated amortization</b>					
<b>At January 1, 2018</b>	<b>-3,727</b>	<b>-1,060</b>	<b>-1,063</b>	<b>-</b>	<b>-5,850</b>
Additions	-353	-1,207	-450		-2,010
<b>Accumulated amortization At December 31, 2018</b>	<b>-4,080</b>	<b>-2,267</b>	<b>-1,513</b>		<b>-7,860</b>
<b>Net value at December 31, 2018</b>	<b>1,049</b>	<b>7,058</b>	<b>2,987</b>	<b>3,300</b>	<b>14,394</b>
<b>Gross value</b>					
<b>At January 1, 2019</b>	<b>5,129</b>	<b>9,325</b>	<b>4,500</b>	<b>3,300</b>	<b>22,254</b>
Currency translation adjustments	14				14
<b>Gross value at December 31, 2019</b>	<b>5,143</b>	<b>9,325</b>	<b>4,500</b>	<b>3,300</b>	<b>22,268</b>
<b>Accumulated amortization and impairment</b>					
<b>At January 1, 2019</b>	<b>-4,080</b>	<b>-2,267</b>	<b>-1,513</b>		<b>-7,860</b>
Additions	-324	-1,218	-450		-1,992
Impairment		-1,847		-3,300	-5,147
<b>Accumulated amortization and impairment at December 31, 2019</b>	<b>-4,404</b>	<b>-5,332</b>	<b>-1,963</b>	<b>-3,300</b>	<b>-14,999</b>
<b>Net value at December 31, 2019</b>	<b>739</b>	<b>3,993</b>	<b>2,537</b>	<b>0</b>	<b>7,269</b>

Amortization of intangible assets are included in research & development expenses and selling, general & administrative expenses in the statement of profit and loss.

The Company did not capitalize development expenses during 2019. During 2018, the company capitalized \$802,000 associated with the improvement of ConfirmMDx and SelectMDx aimed at increased cost efficiency and automation were capitalized and included in internally developed intangible assets.

The In-process R&D resulted from the allocation of the purchase price paid for the acquisition of MDxHealth BV in September 2015 and is related to the development of AssureMDx. Development costs for AssureMDx are included in development assets and are not yet subject for amortization. The Company test the development costs for AssureMDx

and the In-process R&D for any impairment on an annual basis. Considering the uncertainties about the future commercialization of AssureMDx, the Company did impair the entire In-Process R&D for \$3,300,000, in addition to the previously capitalized development expenses for \$1,847,000. The impairment charge has been presented in the line research and development expenses.

**NOTE 10: Property, plant and equipment and right of-use assets** [Back to Notes list](#)

Thousands of \$	Laboratory equipment	Furniture	IT equipment	Leasehold improvements	TOTAL
<b>Gross value</b>					
<b>At January 1, 2018</b>	<b>5,549</b>	<b>270</b>	<b>433</b>	<b>544</b>	<b>6,796</b>
Additions	430		17	8	455
Disposals	-243				-243
<b>Gross value at December 31, 2018</b>	<b>5,736</b>	<b>270</b>	<b>450</b>	<b>552</b>	<b>7,008</b>
<b>Accumulated amortization</b>					
<b>At January 1, 2018</b>	<b>-3,642</b>	<b>-166</b>	<b>-198</b>	<b>-369</b>	<b>-4,375</b>
Additions	-626	-23	-133	-59	-841
Disposals	221				221
<b>Accumulated amortization at December 31, 2018</b>	<b>-4,047</b>	<b>-189</b>	<b>-331</b>	<b>-428</b>	<b>-4,995</b>
<b>Net value at December 31, 2018</b>	<b>1,689</b>	<b>81</b>	<b>119</b>	<b>124</b>	<b>2,013</b>

Thousands of \$	Laboratory equipment	Furniture	IT equipment	Leasehold improvements	TOTAL
<b>Gross value</b>					
<b>At January 1, 2019</b>	<b>5,736</b>	<b>270</b>	<b>450</b>	<b>552</b>	<b>7,008</b>
Additions	22		40	11	73
Disposals	-4		-157		-161
Reclassification to leasing category	-498				-498
<b>Gross value at December 31, 2019</b>	<b>5,256</b>	<b>270</b>	<b>333</b>	<b>563</b>	<b>6,422</b>
<b>Accumulated amortization</b>					
<b>At January 1, 2019</b>	<b>-4,047</b>	<b>-189</b>	<b>-331</b>	<b>-428</b>	<b>-4,995</b>
Additions	-518	-22	-91	-46	-677
Disposals	1		150		151
Reclassification to leasing category	156				156
Exchange rate difference arising	10				10
<b>Accumulated amortization at December 31, 2019</b>	<b>-4,398</b>	<b>-211</b>	<b>-272</b>	<b>-474</b>	<b>-5,355</b>
<b>Net value at December 31, 2019</b>	<b>858</b>	<b>59</b>	<b>61</b>	<b>89</b>	<b>1,067</b>

The right-of-use assets can be presented as follows:

Thousands of \$	Buildings	Vehicles	Materials	TOTAL
<b>Gross value</b>				
<b>At January 1, 2019 before adoption IFRS 16</b>			<b>399</b>	<b>399</b>
Impact of adoption of IFRS 16	1,595	138	-	1,733
<b>At January 1, 2019 after adoption IFRS 16</b>	<b>1,595</b>	<b>138</b>	<b>399</b>	<b>2,132</b>
Additions				
Disposals				
Reclassification to leasing category			498	498
<b>Gross value at December 31, 2019</b>	<b>1,595</b>	<b>138</b>	<b>897</b>	<b>2,630</b>
<b>Accumulated amortization</b>				
<b>At January 1, 2019</b>			<b>-338</b>	<b>-338</b>
Additions	-577	-55	-119	-751
Disposals				
Reclassification to leasing category			-156	-156
<b>Accumulated amortization at December 31, 2019</b>	<b>-577</b>	<b>-55</b>	<b>-613</b>	<b>-1,245</b>
<b>Net value at December 31, 2019</b>	<b>1,018</b>	<b>83</b>	<b>284</b>	<b>1,385</b>

The following amounts related to leases are recognized in profit & loss

Thousands of \$	2019
Depreciation expense	751
Interest expense on lease liabilities	88

#### NOTE 11: Inventories

Thousands of \$/ For the years ended December 31	2019	2018
Raw materials and consumables	1,192	1,807
<b>Total Inventories</b>	<b>1,192</b>	<b>1,807</b>

Inventories are recognized at the lower of cost or net realizable value. Inventories recognized as an expense during the year ended December 31, 2019 amounted to \$ 3,843,000 (2018: \$ 4,296,000). These were included in cost of sales and services.

**NOTE 12: Trade and other receivables****Trade receivables**

Thousands of \$/ For the years ended December 31	2019	2018
Trade receivable	6,645	19,062
<b>Total trade receivable</b>	<b>6,645</b>	<b>19,062</b>

Trade receivables mainly consist of claims due from insurance companies covering the Company's customers.

In 2019, the trade accounts receivable balances were mainly composed of services for ConfirmMDx for Prostate Cancer for \$5,767,000 in comparison with \$16,993,000 in 2018, while SelectMDx for Prostate Cancer represents a total of \$731,000 in 2019 (2018: \$1,808,000). The average Days Sales Outstanding (DSO) stood at 248 days in 2019 compared to 258 days in 2018.

In consideration with the revenue recognition methodology further described under section 2.7 of the financials, our total accounts receivable balance could be presented in relation with the claim date of each case sold.

Thousands of \$/	Months			Total A/R
	1-3 months	4-6 months	7-12 months	
A/R by claim date – SelectMDx USA	204	175	352	<b>731</b>
A/R by claim date – ConfirmMDx USA	2,376	1,162	1,825	<b>5,363</b>
A/R Client bills USA	404			<b>404</b>
A/R by claim date - SelectMDx EU	147			<b>147</b>

**Prepaid expenses and other current assets**

Thousands of \$/ For the years ended December 31	2019	2018
Prepayments	915	617
Deposits	51	54
Recoverable VAT	50	70
Other	4	50
<b>Total prepaid expenses and other current assets</b>	<b>1,020</b>	<b>791</b>

All financial assets carried at amortized cost are shown net of expected credit losses.

**NOTE 13: Cash and cash equivalents** [Back to Notes list](#)

Thousands of \$/ For the years ended December 31	2019	2018
Cash at bank and in hand	22,055	26,203
<b>Total cash and cash equivalents</b>	<b>22,055</b>	<b>26,203</b>

The bank balances and cash held by the Company and short-term bank deposits have an original maturity of less than 3 months. The carrying amount of these assets approximates their fair value.

The Company has restricted cash for an amount of \$42,000 (2018: \$152,000) representing a guarantee with respect to the loan granted by ING (see Note 14 for more information on bank loans). The Company holds no other restricted cash.

**NOTE 14: Loans and Borrowings and lease liabilities** [Back to Notes list](#)

Thousands of \$/ For the years ended December 31	2019	2018
<b>Non-current loans and borrowings</b>		
Loans	9,052	0
Lease liabilities	735	262
<b>Total non-current loans and borrowings</b>	<b>9,787</b>	<b>262</b>

Thousands of \$/ For the years ended December 31	2019	2018
<b>Current loans and borrowings</b>		
Loans	565	147
Lease liabilities	650	117
<b>Total current loans and borrowings</b>	<b>1,215</b>	<b>264</b>

All bank loans prior to 2019, for an initial amount of \$412,000 and a maturity of 2 years, have been used to finance the acquisition of laboratory equipment of the US facilities in Irvine and are today fully reimbursed. The interest rate was fixed by the LIBOR rate in USD with a margin of 1.20%. These loans were secured by a cash pledge.

During the fourth quarter of 2019, the Company entered into a loan facility with Kreos Capital in the amount of €9 million, or approximately \$10 million. The loan term is four years with the first 12 months of interest-only payments followed by 36 months of principal and interest payments. The financial results largely related to the interest charges paid for the loan facility with Kreos Capital for a total of \$194,000. The amortized cost is calculated using the effective interest method, which allocates interests and expenses at a constant rate over the term of the instrument; the effective interest rate for the loan is 12.86%.

The Company has several lease obligations. The leases have terms of 3 to 5 years and some of them include an option to purchase the equipment.

Maturity of loans and borrowings are as follows at the balance sheet date:

Thousands of \$/ For the years ended December 31	2019	2018
<b>Loans</b>		
Within one year	1,443	153
Years two to five	11,109	0
<b>Leases</b>		
Within one year	682	136
Years two to five	741	274

Note: all figures shown in this table are undiscounted and reflect future cash payments.

**NOTE 15: Liabilities arising from financing activities** [Back to Notes list](#)

Thousands of \$/ For the years ended December 31	2019	2018
<b>Gross debt</b>		
Non-current loans and borrowings	9,052	-
Non-current lease liabilities	735	262
Current loans and borrowings	565	147
Current lease liabilities	650	117
<b>Total gross debt</b>	<b>11,002</b>	<b>526</b>

Thousands of \$/ For the years ended December 31	2019	2018
<b>Other financial liabilities</b>		
Other non-current financial liabilities	690	1,045
Other current financial liabilities	909	402
<b>Total other financial liabilities</b>	<b>1,599</b>	<b>1,447</b>

Other financial liabilities were transferred from current liabilities to non-current liabilities as a result of a certain delay in the sale of SelectMDx, being a contractually agreed milestone payment.



A reconciliation of cash and non-cash movements of loans and borrowings, lease liabilities and other financial liabilities is presented below:

	Loans and borrowings		Other financial liabilities	
Thousands of \$/ For the years ended December 31	2019	2018	2019	2018
<b>Opening balance</b>	<b>147</b>	<b>337</b>	<b>1,447</b>	<b>1,544</b>
<b>Cash movements</b>				
Loans and borrowings repaid	-589	-190	-	-
Loans and borrowings received	10,111		-	-
<b>Non-cash movements</b>				
Other movements	-52			
Fair value changes through profit and loss			152	-97
<b>Closing balance</b>	<b>9,617</b>	<b>147</b>	<b>1,599</b>	<b>1,447</b>

	Lease liabilities	
Thousands of \$ / For the years ended December 31	2019	2018
<b>Opening balance</b>	<b>379</b>	<b>547</b>
<b>Cash movements</b>		
Repayment of lease liabilities	-815	-168
<b>Non-cash movements</b>		
Interest accretion	88	
New leases/IFRS 16 adoption	1,733	
<b>Closing balance</b>	<b>1,385</b>	<b>379</b>

**NOTE 16: Contractual obligations** [Back to Notes list](#)

Thousands of \$/ For the years ended December 31	2019	2018
<b>Outstanding commitments for future minimum rent payments, which fall due as follows:</b>		
Within one year	213	907
In the second to fifth year	103	1,358
After five years	-	-
<b>Total contractual obligations</b>	<b>316</b>	<b>2,265</b>

For 2019, we refer to note 10 and 14 for the lease liabilities subsequent adoption of IFRS 16.

Outstanding commitments for future minimum rent payments include rental fees related to leased facilities and equipment for assets not in scope of IFRS 16 for the current year 2019.

These lease contracts can be terminated early with certain indemnity fees. All figures shown assume that the lease contracts will not be terminated early.

#### NOTE 17: Trade and other payables [Back to Notes list](#)

### Trade accounts payable

Thousands of \$/ For the years ended December 31	2019	2018
Trade accounts payable	2,640	4,006
Accruals for invoices to be received	2,318	2,447
<b>Total trade accounts payable</b>	<b>4,958</b>	<b>6,453</b>

### Other current liabilities

Thousands of \$/ For the years ended December 31	2019	2018
Payroll	3,331	4,326
Other accruals	14	32
<b>Total other current liabilities</b>	<b>3,345</b>	<b>4,358</b>

**NOTE 18: Financial instruments and fair value** [Back to Notes list](#)

The table shows the Company's significant financial assets and liabilities. All financial assets and liabilities are carried at amortized cost with the exception of the contingent considerations in relation to acquisitions reported at fair value through profit and loss.

All financial assets and liabilities are considered to have carrying amounts that do not materially differ from their fair value.

Thousands of \$/ For the years ended December 31	2019	2018	Fair value hierarchy
<b>ASSETS</b>			
<b>At amortized cost</b>			
Trade receivables	6,645	19,062	
Other current assets	966	671	
Cash and cash equivalents	22,050	26,203	
<b>Total financial assets</b>	<b>29,661</b>	<b>45,936</b>	
<b>LIABILITIES</b>			
<b>At fair value:</b>			
Other financial liabilities	1,599	1,447	Level 3
<b>Subtotal financial liabilities at fair value</b>	<b>1,599</b>	<b>1,447</b>	
<b>At amortized cost:</b>			
Loans and borrowings	9,617	147	Level 2
Lease liabilities	1,385	379	
Trade payables	4,958	6,453	
<b>Subtotal financial liabilities at amortized cost</b>	<b>15,960</b>	<b>6,976</b>	
<b>Total financial liabilities</b>	<b>17,559</b>	<b>8,426</b>	

**Recognized fair value measurements - Valuation technique and principal inputs**

The fair value of the financial instruments has been determined on the basis of the following methods and assumptions:

- The carrying value of the cash and cash equivalents, the trade receivables, other current assets and the trade payables approximate their fair value due to their short-term character;
- Loans and borrowings (excluding leases) are evaluated based on their interest rates and maturity date. Their fair value approximates their carrying value (level 2).
- Leases are measured at the present value of the remaining lease payments, using a discount rate based on the incremental borrowing rate as of January 1, 2019. Their fair value approximates their carrying value.
- The fair value of contingent consideration payable (presented in the lines other non-current financial liabilities and other current financial liabilities) is based on an estimated outcome of the conditional purchase price/contingent payments arising from contractual obligations (level 3). This is initially recognized as part of the purchase price and subsequently fair valued with changes recorded through profit and loss. The Company used a discount rate of 9.30%. The effect of the fair value measurement is \$152,000 in consolidated income statement.

## Fair value hierarchy :

The Company uses the following hierarchy for determining and disclosing the fair value of financial instruments by valuation technique:

Level 1: quoted prices in active markets for identical assets and liabilities;

Level 2: other techniques for which all inputs which have a significant effect on the recorded fair value are observable, either directly or indirectly; and

Level 3: techniques which use inputs that have a significant effect on the recorded fair value that are not based on observable market data.

No financial assets or financial liabilities have been reclassified between the valuation categories during the year.

### NOTE 19: Earnings per share [Back to Notes list](#)

The basic earnings per share is calculated by dividing the net result attributable to shareholders by the weighted average number of shares outstanding during the year.

Years ended December 31	2019	2018
Loss for the year, in thousands of \$	-43,100	-32,450
Basic and diluted EPS, in \$	-0.69	-0.56

Weighted average number of shares	2019	2018
Weighted average number of shares for basic and diluted EPS	62,579,345	57,612,878

At December 31, 2019 and 2018, the Company has potential dilutive shares in the form of warrants. The Company is reporting a net loss. As a result, the warrants have an anti-dilutive effect rather than a dilutive effect.

### NOTE 20: Financial Risk Management [Back to Notes list](#)

## Capital management

The Company manages its capital with the aim of ensuring that the Company can continue to operate in continuity.

Capital is comprised of equity attributable to shareholders, borrowings and cash and cash equivalents. The Company aims to maintain a strong capital base in order to uphold investor and creditor confidence and to sustain the future development of the business. The Company's objectives when managing capital are to maintain sufficient liquidity to meet its working capital requirements, fund capital investment and purchases and safeguard its ability to continue operating as a going concern. The Company monitors capital regularly to ensure that the statutory capital requirements are met and may propose capital increases to the shareholders' meeting to ensure the necessary capital remains intact.

## Credit risk

Credit risk arises from cash and cash equivalents, short-term bank deposits, as well as credit exposure to collaboration partners. Credit risk refers to the risks that counterparty will default on its contractual obligations resulting in financial loss to the Group.

At the end of 2019, the Company operated with more than 1,000 different customers, systematically reducing credit risk compared to prior periods.

In the US healthcare system, and particularly within the molecular diagnostic CLIA laboratory industry, where there are rapid technological advances in diagnostic services, companies provide services to healthcare professionals and their patients, while being reimbursed from commercial and governmental insurance systems. Often these services are provided out of network and without supplier contracts. As a result, there is reimbursement risk, separate from credit risk that is characterized by uncertainty in reimbursement value, delays in payment, and ultimately non-payment. This impacts the Company's revenue recognition and cash collections.

In addition to reimbursement risk associated with commercial third-party payors, credit risk may also arise from amounts due directly from patients. In many cases, payors will cover the entire cost of testing. The ConfirmMDx test falls under the Clinical Laboratory Fee Schedule, so there is no co-payment, co-insurance or deductible for patients covered under traditional Medicare. However, patients covered by commercial insurance companies may be responsible for a co-payment, co-insurance, and/or deductible depending on the health insurance plan and individual patient benefit. Credit risk exists for those patients who cannot meet their co-payment or deductible portions.

Customer's compliance with agreed credit terms is regularly and closely monitored. Trade accounts receivable amounted to \$6,645,000 at December 31, 2019 and no allowance for expected credit loss was recorded. The Company applies the simplified approach to providing for expected credit losses (ECL) prescribed by IFRS 9, which requires the use of the lifetime expected loss provision for all trade receivables. No ECL has been recorded for other financial assets carried at amortized cost as there is no related credit risk.

The credit risk on cash and cash equivalents \$22,050,000 is limited given that the counterparties are banks with high credit scores attributed by international rating agencies.

## Interest risk

In the course on 2019, the Company has entered into a 48-months loan agreement for a total amount of €9 million. The amortized cost is calculated using the effective interest method, which allocates interests and expenses at a constant rate over the term of the instrument; the effective interest rate for the loan is 12.86%.

Considering the fixed interest rate, the Company is not exposed to interest risk, thus did not perform any sensitivity analysis.

## Currency risk

Considering the continuing development of the commercial activities in the US market, the Company has decided to change its presentation currency from the EURO to the US Dollar as of January 1, 2013. The functional currency changed also from the EURO to the US Dollar as of July 1, 2014. In consequence, the currency risk is concentrated on European operations.

The monetary items at December 31, 2019 in EURO are composed of cash on hand of €15,859,000.

The Company performed a sensitivity analysis of an increase/decrease of exchange rate on operations of 10%. The exposure of operations to the currency risk is limited to the net amount of €11,800,000 (€775,000 revenue and €12,575,000 costs), resulting in a potential gain of €1,355,000 in case of an increase of the USD/Euro exchange rate by 10%, and a potential loss of €1,108,000 in case of a decrease of the exchange rate by 10%.

## Liquidity risk

The Company manages liquidity risk by maintaining adequate reserves and by continuously monitoring forecast and actual cash flows and matching the maturity profiles of financial assets and liabilities. At the date of this document, the Company has one loan agreement with banks and five financial leases (see notes 17 and 18) and no derivative instruments.

For the years ended December 31, 2019	Less than 1 year	Between 1 and 2 years	Between 2 and 5 years	Total contractual cash flows	Carrying amount
<b>Non derivatives</b>					
Trade payables	4,958			4,958	4,958
Borrowings	1,443	3,856	7,253	12,552	9,617
Lease liabilities	682	490	251	1,423	1,385
<b>Total</b>	<b>7,083</b>	<b>4,346</b>	<b>7,504</b>	<b>18,933</b>	<b>15,960</b>

*Note: all figures shown in this table are undiscounted and reflect future cash payments.*

For the years ended December 31, 2018	Less than 1 year	Between 1 and 2 years	Between 2 and 5 years	Total contractual cash flows	Carrying amount
<b>Non derivatives</b>					
Trade payables	6,453			6,453	6,453
Borrowings	153			153	147
Lease liabilities	136	217	57	410	379
<b>Total</b>	<b>6,742</b>	<b>217</b>	<b>57</b>	<b>7,016</b>	<b>6,979</b>

*Note : all figures shown in this table are undiscounted and reflect future cash payments*

## Other risks

The Company subscribes to certain insurance policies to cover matters such as (i) fire, theft, and other damage to its assets, (ii) product and liability insurance and clinical trial insurance, and (iii) D&O insurance. To date, no significant claims have been made under these insurance policies and there is no guarantee that the insurances will cover all damages if they should ever occur.

To date, the Company has received several government grants for various R&D projects. Some of these grant amounts can be re-claimed if the Company does not fulfill all the conditions of the grant agreements.

**NOTE 21: Share capital and reserves** [Back to Notes list](#)

At December 31, the Company's share capital was represented by the following number of shares (units). Only one class of shares (common shares) exists and they have no par value.

For the Years ended December 31	2019	2018
Common shares	70,528,525	59,939,289
<b>Total outstanding shares</b>	<b>70,528,525</b>	<b>59,939,289</b>

The capital stock and the issuance premium at December 31 amounted to the following:

For the Years ended December 31	Thousands of \$/		Thousands of €/	
	2019	2018	2019	2018
Share Capital as per statutory accounts	70,717	61,295	56,260	47,813
Capital Increase costs	-7,876	-7,418	-6,506	-6,085
Share capital under IFRS	62,841	53,877	49,754	41,728
Issuance premium	136,349	135,731	112,078	111,524
Share capital and issuance premium	199,190	189,608	161,832	153,252

The share capital and issuance premium increased in 2019 via a placement of 10,589,236 new shares in October 2019 for a gross amount of \$10 million (€9 million). The share capital and issuance premium increased in 2018 via a placement of new shares in March 2018 for a gross amount of \$44 million.

The history of the Share Capital can be found in "General Information; Capital and Shares".

**NOTE 22: Retirement benefit schemes** [Back to Notes list](#)

The Company operates defined contribution schemes for all its qualifying employees. The assets of these schemes are held separately from those of the Company in designated funds.

A total cost of \$637,000 in 2019 (2018: \$827,000) represents contributions payable to these schemes by the Company at rates specified in the rules of the plans.

The employees of the Company in Belgium are members of a state-managed retirement benefit scheme operated by the government (i.e., legal pension) and are members of a bank-operated private pension scheme. The Company is required to contribute a specified percentage of payroll costs to the retirement benefit scheme to fund the benefits. The obligation of the Company with respect to the retirement benefit scheme is to make the specified contributions.

Because the Company must guarantee the statutory minimum return on these plans, not all actuarial and investment risks relating to these plans are transferred to the insurance company or pension fund managing the plans. The Company has considered the potential impact of the employer's obligation to guarantee a minimum return and that this was assessed not to be significant.



**NOTE 23: Share based payments** [Back to Notes list](#)

This section provides an overview of the outstanding warrants as of December 31, 2019. The warrants were created within the context of stock-based incentive plans for employees, directors and consultants of the Company.

The Company has created several pools of warrants under stock option plans for grant to eligible employees, Directors, and consultants. On May 12, 2004 (30,000), July 12, 2005 (15,000), March 22, 2006 (66,700), November 8, 2006 (47,500), April 18, 2007 (55,100), May 25, 2007 (50,000), May 30, 2008 (61,000), January 2, 2009 (120,500), June 21, 2010 (145,000), May 27, 2011 (225,000), March 15, 2012 (195,000), June 15, 2012 (700,000), June 23, 2014 (1,500,000), June 19, 2017 (2,500,000), June 21, 2019 (3,000,000). In aggregate 8,710,800 warrants were issued, subject to warrants being granted to and accepted by the beneficiaries. Of these 8,710,800 warrants, (i) 1,587,490 warrants were terminated or lapsed, (ii) 577,123 warrants were exercised, (iii) 4,250,687 warrants were granted but not yet exercised, and (iv) 2,295,500 warrants were not yet granted by the Company. For the year 2019, 652,687 warrants (2018: 233,375) were terminated or lapsed, no warrants were exercised, and 37,624 warrants (2018: 352,689) were vested. As a result, as at December 31, 2019, there are 4,250,687 warrants outstanding, entitling their holders to subscribe to 4,250,687 shares of the Company.

Number of potential shares from outstanding warrants	2019	2018
At January 1	2,124,374	2,123,750
Number of warrants cancelled/forfeited during the year	-652,687	-233,375
Number of warrants exercised during the year	0	0
Number of warrants granted during the year	2,779,000	234,000
<b>At December 31</b>	<b>4,250,687</b>	<b>2,124,375</b>

The warrants are granted to employees (mainly), consultants or directors of the Company and its subsidiaries. Each warrant entitles its holders to subscribe to one new share of the Company at a subscription price determined by the board of directors, within the limits decided upon at the occasion of their issuance.

The warrants issued have generally a term of ten years as of issuance. Upon expiration of their term, the warrants become null and void.

In general, the warrants vest in cumulative tranches of 25% per year, provided that the beneficiary has provided at least one year of service. However, there are certain exceptions to this rule which are, if applicable, specified in the relevant stock option plans. The 30,000 warrants granted under the May 2011 Stock Option Plan to the CEO became vested immediately on the date of grant (i.e. December 7, 2010). The warrants granted under the May 2012 Stock Option Plan and under the June 23, 2014 Stock Option Plan to directors all vest on the date of the annual meeting that takes place in the calendar year following the calendar year in which they were granted, provided that the mandate of the relevant director has not ended or been terminated. The warrants granted under the May 2012 Stock Option Plan and under the June 23, 2014 Stock Option Plan to beneficiaries who are not directors all vest in instalments of 25% per year, the first tranche of 25% vesting on the first anniversary date of the date of grant and the following tranches vesting on a quarterly basis.

The table below presents the outstanding warrants and their exercise price at the end of each accounting year covered by the financial statements:

		<b>Warrants</b>	<b>Weighted average exercise price (€)</b>	<b>Potential shares from exercise of warrants</b>	<b>Weighted average exercise price per potential share (€)</b>
	Granted in 2018	234,000	2.68	234,000	2.68
Outstanding 31	December 2018	2,124,375	4.21	2,124,375	4.21
	Granted in 2019	2,779,000	1.35	2,779,000	1.35
Outstanding 31	December 2019	4,250,687	2.35	4,250,687	2.35
Exercisable at 31	December 2019	1,438,250	3.90	1,438,250	3.90

The following table provides an overview of the outstanding potential shares from warrants per personnel category at December 31, 2019 and 2018:

<b>Category</b>	<b>2019</b>	<b>2018</b>
Executive Director	1,500,000	200,000
Non-Executive Directors	282,000	258,000
Management team (excluding the Executive Director)	1,005,000	652,500
Other employees, consultants, and former service providers	1,463,687	1,103,875
<b>Total outstanding at December 31, 2019</b>	<b>4,250,687</b>	<b>2,124,375</b>

The share-based compensation expense recognized in the statement of comprehensive income is given below as is the cumulated amount per the consolidated statement of financial position:

<b>Thousands of \$/ Years ended December 31</b>	<b>2019</b>	<b>2018</b>
Share-based compensation	872	1,006
Cumulated Share-based compensation	8,090	7,218

The Cumulated Share-based compensation amount is part of the Total Shareholders' Equity on the balance sheet. This amount is presented on the balance sheet for both exercised and non-exercised warrants.

The weighted average exercise price of all outstanding warrants (vested and non-vested warrants; assuming 1 warrant = 1 share) is €2.35 or \$ conversion 2.64 at December 31, 2019 (€4.21 or \$ conversion 4.82 at December 31, 2018). The weighted average remaining contractual life of all outstanding warrants at the end of 2019 is 6.74 years (2018: 5.08 years).

The fair value of each warrant is estimated on the date of grant using the Black-Scholes methodology with the following assumptions:

Dates	Number of warrants granted		Exercise price (€)	Expected dividend Yield	Expected stock price volatility	Risk-free interest rate	Expected duration (months)	
	to Belgian benef.	to other benef.					to Belgian benef.	to other benef.
30-May-08	12,000	37,000	€ 9.10	-	52.30%	4.92%	82.10	61.10
02-Jan-09	63,400	53,200	€ 6.32	-	57.24%	3.98%	74.08	62.88
21-Jun-10	135,000	10,000	€ 2.07	-	76.17%	3.40%	51.35	33.34
27-May-11	100,000	125,000	€ 1.71	-	68.81%	4.15%	76.21	58.19
15-Mar-12	75,000	120,000	€ 1.72	-	67.74%	3.43%	78.57	60.56
15-Aug-12	12,000	24,000	€ 1.52	-	54.50%	2.57%	73.54	61.54
14-Sep-12	-	85,000	€ 1.65	-	55.58%	2.59%	72.56	60.56
01-Dec-12	-	10,000	€ 2.19	-	57.13%	2.19%	75.98	57.99
01-Jan-13	65,000	107,000	€ 2.00	-	57.13%	2.09%	80.97	62.92
01-Feb-13	-	23,000	€ 2.26	-	49.99%	2.39%	79.96	61.91
01-Apr-13	-	5,000	€ 2.30	-	51.52%	2.18%	78.02	59.97
01-May-13	-	15,000	€ 2.13	-	49.75%	1.93%	77.03	58.98
31-May-13	12,000	18,000	€ 2.05	-	49.62%	2.22%	76.04	57.99
12-Mar-14	76,000	177,000	€ 3.60	-	47.75%	2.24%	72.69	54.67
01-Apr-14	-	12,000	€ 4.32	-	48.82%	2.21%	72.03	54.02
30-May-14	18,000	18,000	€ 4.25	-	48.68%	1.86%	70.09	52.08
01-Jun-14	-	4,000	€ 4.24	-	48.81%	1.86%	70.03	52.01
01-Jul-14	-	15,000	€ 4.02	-	48.58%	1.72%	69.04	51.02
1-avr-15	-	4,000	€ 5.02	-	47.42%	0.40%	60.03	47.97
23-Jun-14	12,000	12,000	€ 4.13	-	48.12%	1.78%	75.32	63.29
10-Oct-14	-	17,500	€ 4.01	-	46.93%	1.01%	69.73	57.70
9-Feb-15	60,000	95,000	€ 4.49	-	46.75%	0.62%	79.73	61.71
29-May-15	20,000	30,000	€ 4.91	-	46.52%	0.81%	64.14	52.11
1-Apr-15	-	3,000	€ 5.02	-	47.42%	0.40%	72.03	54.02
1-May-15	-	20,000	€ 5.05	-	46.59%	0.62%	71.05	53.03
1-Jun-15	-	6,000	€ 4.90	-	46.58%	0.81%	70.03	52.01
1-Jul-15	-	4,000	€ 4.62	-	47.02%	1.27%	69.04	51.02
1-Aug-15	-	4,000	€ 4.64	-	46.54%	0.98%	68.02	50.01
1-Sep-15	-	85,000	€ 4.24	-	49.31%	1.15%	73.02	48.99
1-Oct-15	-	8,000	€ 4.20	-	48.99%	0.90%	72.03	54.02
1-Nov-15	-	4,000	€ 3.81	-	50.88%	0.92%	71.01	52.99
1-Dec-15	-	18,000	€ 3.89	-	51.18%	0.85%	70.03	52.01
1-Feb-16	-	10,000	€4.13	-	51.18%	0.85%	67.99	49.97
4-Feb-16	50,000	134,000	€3.78	-	52.49%	0.72%	67.89	49.87
2-Apr-16	-	52,000	€3.62	-	53.40%	0.58%	65.33	53.33
29-May-16	30,000	40,000	€4.13	-	51.85%	0.54%	64.11	52.11

1-Jan-16	-	4,000	€3.79	-	51.12%	1.06%	69.01	50.99
1-Jun-16	-	2,000	€3.43	-	53.73%	0.49%	64.01	52.01
1-Aug-16	-	4,000	€3.62	-	53.51%	0.16%	62.01	50.01
21-Oct-16	-	20,000	€4.44	-	54.19%	0.28%	59.34	47.34
22-Jan-16	-	20,000	€3.83	-	52.81%	0.86%	68.32	56.32
1-Dec-16	-	22,000	€4.65	-	54.16%	0.75%	57.99	39.98
1-Jan-17	-	19,000	€4.56	-	53.84%	0.73%	56.98	50.96
1-Mar-17	-	95,000	€5.26	-	52.62%	0.68%	55.04	49.02
1-Apr-17	-	18,000	€5.41	-	51.80%	0.81%	54.02	48.00
11-Apr-17	20,000	200,000	€5.35	-	51.83%	0.72%	65.68	47.67
1-Jun-17	-	2,000	€5.01	-	51.86%	0.59%	52.01	52.01
1-Jul-17	-	22,000	€4.96	-	50.94%	0.77%	63.02	44.98
29-Jul-17	-	10,000	€4.72	-	50.95%	0.87%	50.10	44.05
1-Sep-17	-	34,000	€4.92	-	48.08%	0.71%	60.99	42.97
1-Oct-17	-	70,000	€4.80	-	47.32%	0.76%	53.98	41.95
2-Nov-17	-	99,000	€4.61	-	45.23%	0.66%	52.93	40.90
1-Dec-17	-	6,000	€3.92	-	46.50%	0.56%	51.98	39.98
20-Jun-17	30,000	30,000	€4.97	-	51.57%	0.59%	81.40	63.39
27-Jun-17	250,000	-	€4.98	-	51.04%	0.66%	81.17	63.16
01-Apr-18	-	42,000	€3.77	-	46.08%	0.76%	54.02	42.02
01-May-18	-	8,000	€3.64	-	46.27%	0.82%	53.03	41.03
01-Jun-18	-	2,000	€3.79	-	46.15%	0.77%	52.01	40.01
01-Jun-18	50,000	30,000	€4.97	-	46.15%	0.77%	52.01	40.01
01-Aug-18	-	70,000	€3.74	-	44.09%	0.79%	62.01	55.96
01-Jun-18	-	8,000	€3.66	-	44.04%	0.73%	48.99	36.99
01-Oct-18	-	4,000	€3.10	-	46.56%	0.88%	60.00	53.95
05-Dec-18	-	20,000	€1.73	-	57.56%	0.79%	45.86	33.86
24-Jan-19	-	191,000	€1.64	-	67.56%	0.77%	62.24	50.20
16-May-19	-	1,508,000	€1.49	-	75.78%	0.38%	58.55	46.52
01-Nov-19	-	8,000	€1.01	-	82.15%	0.00%	64.99	46.98
01-Dec-19	-	12,000	€1.02	-	81.95%	0.00%	64.01	45.99
01-Jul-19	60,000	20,000	€1.28	-	78.70%	0.07%	69.01	51.02
24-Jul-19	-	980,000	€1.24	-	78.64%	0.00%	68.25	50.27

The above inputs for the Black-Scholes model have been determined based on the following:

- The dividend return is estimated by reference to the historical dividend payment of the Company. Currently, this is estimated to be zero as no dividends have been paid since inception.
- The expected volatility was determined using the average volatility of the stock over the last two years at the date of grant.
- Risk-free interest rate is based on the interest rate applicable for the 10Y Belgian government bond at the grant date





**NOTE 24: Related parties** [Back to Notes list](#)

Transactions between MDxHealth SA, MDxHealth Inc. and MDxHealth B.V. which are related parties, have been eliminated on consolidation and are not disclosed in this note. Since 2012, the intercompany services relate to royalties paid by MDxHealth Inc. to MDxHealth SA and to interest on intercompany loans. In 2019, the services charged by the parent company to the subsidiary amounted to \$4,969,000.

Transactions between the Company and its employees, consultants or Directors are described below. There were no other related party transactions.

## Remuneration of key management personnel

During the year ended December 31, 2019, the executive management team included four members:

1. Chief Executive Director, Mr. Michael McGarrity
2. Executive Vice President of Corporate Development & General Counsel, Mr. Joseph Sollee
3. Chief Finance Officer, Mr. Ron Kalfus
4. Chief Commercial Officer, Mr. John Bellano

Their combined remuneration package, including employer taxes, amounted to the following:

Thousands of \$/ except per personnel, warrants & share amounts For the Years ended December 31	2019	2018
Number of management members and Executive Directors	4	4
Short-term employee benefits	1,101	1,593
Post-employment benefits	26	45
Other employment costs	65	68
Termination benefits	1,111	0
Total benefits	2,303	1,706
IFRS share-based compensation expense	34	392
Shares owned	-	199,590
Number of warrants offered	2,330,000	0
Cumulative outstanding warrants	2,505,000	705,000
Exercisable warrants	160,000	426,875

In the course of 2019, the management team of the Company was renewed and the total cost for these changes amount to \$1,111,000. The total cost for the actual management team amounts to \$1,192,000.

In 2019, in aggregate for the five members of the executive management team, no warrants were exercised, and 2,330,000 new warrants were granted and accepted. The annualized IFRS cost for existing warrants is \$34,000.

In 2018, in aggregate for the four members of the executive management team, no warrants were exercised, and no new warrants were granted and accepted. The annualized IFRS cost for existing warrants is \$392,000.

No loans, quasi-loans or other guarantees are outstanding with members of the executive management team.

## Remuneration of the Board

The total remuneration of the Board of Directors (including the Executive Director) in 2019 and 2018 was \$484,000, and \$713,000 respectively (excluding VAT, stock-based compensation and reimbursement of expenses). No advances or credits have been granted to any member of the Board of Directors. None of the members of the Board of Directors have received any non-monetary remuneration other than warrants as disclosed above.

## Transactions with Non-Executive Directors

Since 2012, the Non-Independent Directors do not receive a fee payment for attending and preparing for Board meetings or for assisting the Company with Board matters. They receive reimbursement for expenses directly related to the Board meetings, totaling less than \$24,000 in 2019.

The Independent Directors receive a fee for attending and preparing meetings of the Board of Directors and for assisting the Company with Board matters, and they receive reimbursement for expenses directly related to the Board meetings. In 2019 and 2018, respectively \$135,000 and \$176,000 were paid as fees and expense reimbursement to independent members of the Board of Directors.

A total of 70,000 warrants were granted to Non-Executive Directors in 2019 and no warrants were exercised in 2019.

**NOTE 25: Significant agreements, commitments and contingencies** [Back to Notes list](#)

## Fair value of Other financial liabilities

On September 18, 2015, MDxHealth acquired MDxHealth BV (former NovioGendix), a Dutch molecular diagnostic research and service company with expertise in the urological oncology. The terms of the acquisition consisted of initial consideration paid in 1,086,956 shares of MDxHealth common stock, issued at €4.14 representing the average closing price of the Company's shares on Euronext Brussels during a period of 30 days ending on September 17, 2015. In addition to this equity, additional cash consideration of €250,000 was paid. On top of the acquisition price, MDxHealth is committed to pay future milestone fees. The Company paid €1,000,000, being \$1,105,000 regarding these milestone fees in 2017. In 2019 the contingent consideration has been adjusted for \$152,000 relating to the value of money in time. The fair value of this contingent consideration as of December 31, 2019 is estimated at \$1,599,000 over the period 2019-2021 (2018: \$1,447). The Company is contractually required to pay at maturity to the holder of the obligation the amount of maximum \$2,200,000.

## Collaborative research agreements and clinical research agreements

The Company has entered into numerous agreements with universities, medical centers and external researchers for research and development work and for the validation of the Company's technology and products. These agreements typically have durations of one to three years. The Company must pay fixed fees to the collaborators and in exchange typically receives access and rights to the results of the work.

MDxHealth collaborates on research and clinical development with many of the world's leading academic and government cancer research institutes. These important relationships provide the Company with additional resources and expertise for clinical marker validation as well as access to patient samples for testing. MDxHealth's collaborators include such prestigious institutions as Johns Hopkins University Medical Institutions (US), Duke University Medical Center (US), Harvard Medical School (US), Cleveland Clinic (US), University of Colorado (US), University of California at Los Angeles (US), Radboud University (The Netherlands) and University of Gent (Belgium) among others.



## Intellectual property in-licensing agreements

The Company has entered into numerous agreements with universities and companies for in-licensing intellectual property. These agreements typically require the Company to pay an up-front fee, annual maintenance fees and/or minimum annual royalty fees, legal fees related to the patents, and certain milestone and royalty fees if the patents are eventually used in a commercialized product. In addition, the Company must provide the licensor with periodic reports.

## Commercial and intellectual property sub-licensing agreements

The Company has entered into numerous partnering and sub-licensing agreements. In regard to the Company's developed tests, the Company has entered into a range of marketing and sales arrangements with commercial entities. These important relationships provide the Company with additional resources and infrastructure to expand the geographic reach and awareness of the Company's solutions, primarily in relation to the ConfirmMDx and SelectMDx tests. MDxHealth's marketing partners include Cerba Healthcare (Belgium), Ferrer Internacional (Spain), Teva Pharmaceuticals (Israel), and SouthGenetics (South and Central America), LifeLabs (Canada) and, in the US, LabCorp, Miraca Life Sciences, Bostwick Laboratories.

In regard to intellectual property that MDxHealth has developed or improved, MDxHealth has sublicensed certain of its non-core epigenetic technologies to commercial partners, several of whom have launched products that generate royalties and other fees. These sublicenses include:

- an exclusive sublicense to Laboratory Corporation of America (LabCorp) for the MGMT test (for the North American market only, of indefinite duration, and limited to service testing only). MDxHealth retained certain rights to develop and commercialize the MGMT test as a companion diagnostic on a worldwide basis. LabCorp began to commercialize the MGMT test in North America in 2008.
- non-exclusive sublicense agreements for the Company's patented methylation specific PCR (MSP) technology for diagnostic applications, in exchange for certain license fees and running royalties, to several partners including oncnostics GmbH, Qiagen GmbH and Takara Bio.

## Litigation

As of the date of this document and as far as MDxHealth is aware, the Company is not involved in any material legal proceedings.

### NOTE 26: Subsequent events [Back to Notes list](#)

In December 2019, a novel strain of coronavirus causing COVID-19 was reported to have surfaced in Wuhan, China and has since spread to other parts of the world. On March 11, 2020, the World Health Organization declared the outbreak a pandemic. The COVID-19 pandemic is affecting the United States and global economies and may affect the Company's operations and those of third parties on which the Company relies. However, the impact on the business is unknown at this time. State and local authorities in the United States, Europe, and other countries, have since forced many businesses to temporarily shut down in an attempt to slow the spread of the virus, and citizens around the world are being told by public officials to stay at home and practice "social distancing". Global stock markets have reacted negatively, and many economists are projecting an economic slowdown, at least in the near term, even if governments take emergency relief measures. Regardless of the extent of any economic slowdown, the outbreak could impact the Company's ability to develop business, conduct operations, and obtain components used in its business. The situation is constantly evolving, however, so the extent to which the COVID-19 outbreak will impact business and the economy is highly uncertain and is extremely difficult to predict. Accordingly, the Company cannot accurately predict the extent to

which its 2020 financial condition and results of operations will be affected, however, management expects the impact to be limited and not to affect the Company's ability to continue as a going concern.

On April 20, 2020, the Company announced that its U.S. subsidiary, MDxHealth Inc., has entered into a "Paycheck Protection Program" (PPP) loan with the U.S. Small Business Administration (SBA) in the amount of \$2.3 million as part of the U.S. Coronavirus Aid, Relief, and Economic Security (CARES) Act. The loan has a term of two years and carries an interest rate of 1.0% per year. Payments on the loan are deferred for the first six months following disbursement of the loan, with principal and interest payments beginning on the seventh month. Interest on the loan continues to accrue during the six-month deferment period.

On April 24, 2020, the Company entered into a subscription agreement with MVM V LP and MVM GP (No.5) LP (collectively "MVM") pursuant to which MVM agreed to provide an equity investment to the Company for an aggregate amount of EUR 12.7 million or approximately \$14 million. The equity investment will consist of a subscription of 20,162,924 new ordinary shares of the Company at an issue price of EUR 0.632 per share, representing a 5% discount to the 45-day volume weighted average price. The transaction is subject to limited customary conditions precedent, and is expected to close on or about 15 May 2020.

#### NOTE 27: Subsidiaries [Back to Notes list](#)

The Company has the following two wholly-owned direct subsidiaries:

##### MDxHealth Inc.

Address	15279 Alton Parkway – Suite 100 – Irvine, CA 92618
Incorporation Date	April 14, 2003
Number of employees	158 at December 31, 2019, 164 at December 31, 2018, and 200 at December 31, 2017.

##### MDxHealth B.V.

Address	Transistorweg 5, 6534 AT Nijmegen, The Netherlands
Incorporation Date	October 18, 2006
Incorporated into MDxHealth on	September 18, 2015
Number of employees	11 at December 31, 2019, 12 at December 31, 2018 and 12 at December 31.

#### NOTE 28: Principal audit fees and services [Back to Notes list](#)

During the past fiscal year, in addition to their usual activity, the statutory auditor performed additional activities on behalf of the Company mainly for the issuance of special reports related to warrant plans, grant report certification, for participation to the audit committees and for participation to special projects.

The Company expensed €111,000 (USD equivalent \$125,000) in fees to the auditor in 2019. The fees are broken down as follows:

- Audit fee for statutory and consolidated financials of € 99,000 (\$111,000)
- Audit related services (legal missions) € 12,000 (\$14,000)

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# Auditor's opinion

## STATUTORY AUDITOR'S REPORT TO THE GENERAL MEETING OF MDXHEALTH SA FOR THE YEAR ENDED 31 DECEMBER 2019 (CONSOLIDATED FINANCIAL STATEMENTS)

In the context of the statutory audit of the consolidated financial statements of MDxHealth SA ('the Company') and its subsidiaries (together referred to as 'the Group'), we hereby present our statutory auditor's report. It includes our report on the audit of the consolidated financial statements and the other legal and regulatory requirements. This report is an integrated whole and is indivisible.

We have been appointed as statutory auditor by the general meeting of 26 May 2017, following the proposal formulated by the board of directors issued upon recommendation of the Audit Committee. Our statutory auditor's mandate expires on the date of the General Meeting deliberating on the financial statements closed on 31 December 2019. We have performed the statutory audit of the consolidated financial statements of MDxHealth SA for fourteen consecutive years.

### REPORT ON THE CONSOLIDATED FINANCIAL STATEMENTS

#### *Unqualified opinion*

We have performed the statutory audit of the Group's consolidated financial statements, which comprise the consolidated statement of financial position as at 31 December 2019, and the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended, and notes to the consolidated financial statements, including a summary of significant accounting policies and other explanatory information, and which is characterized by a consolidated statement of financial position total of 40,268 (000) USD and for which consolidated income statement and other comprehensive income shows a loss for the year of 43,100 (000) USD.

In our opinion, the consolidated financial statements give a true and fair view of the Group's net equity and financial position as at 31 December 2019, as well as of its consolidated financial performance and its consolidated cash flows for the year then ended, in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union and with the legal and regulatory requirements applicable in Belgium.

#### *Basis for unqualified opinion*

We conducted our audit in accordance with International Standards on Auditing (ISA) as applicable in Belgium. Our responsibilities under those standards are further described in the 'Statutory auditor's responsibilities for the audit of the consolidated financial statements' section in this report. We have complied with all the ethical requirements that are relevant to the audit of consolidated financial statements in Belgium, including those concerning independence.

We have obtained from the administrative body and company officials the explanations and information necessary for performing our audit.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

## **Key audit matters**

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the consolidated financial statements of the current year. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

## **Revenue recognition**

### *Discussion of the matter*

As described in notes 2.7 and 3 of the financial statements, the majority of the Group's revenue is derived from laboratory services with revenue recognized at a point in time when control of the services has transferred to the customer. This is generally when the test results are delivered to the customer. Other Group's revenue is derived from license fees, royalties and government grants.

The group's revenue recognition model includes critical accounting estimates based on management judgment. These estimates and underlying judgments are continuously revisited based on updated historical experience and the expected evolution of collections from third party payers.

Revenue recognition was significant to our audit procedures, because of its financial impact on the consolidated annual accounts, and the significant level of management judgment required in making the accounting estimates.

### *Procedures performed*

Our audit procedures included, amongst others:

- We tested the Group's internal control procedures on revenues and evaluated the Group's assumptions and estimates used in assessing revenue recognition, in particular with respect to completeness, existence and accuracy.
- We tested the existence of persuasive evidence of underlying agreements and contracts and we substantively tested and challenged the underlying calculations, key assumptions and estimates used in the revenue model.
- We evaluated the reasonableness of the calculations of the ratio of claims collected in relation to claims billed, and of the trend of such ratio.
- We considered the historical accuracy of accrued amounts of revenue and used the information obtained as evidence for evaluating the appropriateness of the assumptions made in the current year including how these compare to the experience in previous years.
- We reviewed the adequacy of the Group's disclosures in notes 2.7 and 3 in respect of the use of estimates and judgments in the revenue recognition model.

## Transition to IFRS 16, Leases

### *Discussion of the matter*

IFRS 16 Leases has been adopted from 1 January 2019. Under IFRS 16, leases are accounted for based on a 'right-of-use model'. The model reflects that, at lease commencement, a lessee has a financial obligation to make lease payments to the lessor in exchange for its right to use the underlying asset during the lease term. The Group elected to apply the modified retrospective approach, not restating comparatives for the 2018 reporting period. The reclassifications and adjustments arising from the new lease standard were recognized in the opening balance sheet on 1 January 2019. The initial recognition led to an increase in fixed assets of 1,733 (000) USD, and to an increase in lease liabilities of the same amount as at 1 January 2019. We refer to note 2.5.1 New Standards, Interpretations and Amendments adopted by the Company, note 10 Property, plant & equipment and right-of-use assets and to the accounting policy in note 2.13. We considered this to be a key audit matter due to the significant related impact on some key accounting metrics.

### *Procedures performed*

To assess the Group's process for estimating the impact of adopting IFRS 16, we performed the following audit procedures, amongst others:

- We have assessed the design of the systems and processes set up by management to account for transactions in accordance with the new standard and used in determining the impact of the initial application of IFRS 16;
- We have reviewed the accounting policy and challenged management on their judgments made in the process of applying the IFRS 16 accounting policy;
- We have reviewed the complete identification of leases as well as the consistent and accurate compilation of lease master data on implementation date;
- We have obtained support from management for their determination of the discount rates used to calculate the present value of the lease payments used to measure the lease liabilities; we have considered similarity of benchmark borrowing and securing assets, validated market inputs, and examined assumptions made by management;
- We have performed independent recalculation of the right-of-use assets and lease liabilities calculated by the system for a sample of leases.

## Financial Funding

### *Description of the matter*

In note 2.3 of the financial statements, the Group has disclosed that based on its current scope of activities and available funding, it estimates that as at 31 December 2019 it has sufficient liquidity to continue as a going concern.

Given the high cash burn rate inherent to the sector the Group is operating in, we consider financial funding a key audit matter requiring heightened auditors' attention.

### *Procedures performed*

Our audit procedures included the following, amongst others:

- We obtained the business plan and the cash forecasts for the years 2020 and 2021, and reviewed them for reasonableness;
- We challenged the assumptions underlying these budget and cash forecasts, especially with respect to the expected level of revenue, collections and operating expenses;

- We compared the total of expected revenues included in the budget and cash forecasts with those expected from prior years' experience;
- We discussed with management any potential future financing possibilities and assessed their reasonableness;
- We considered the impact of the MVM agreement of 24 April 2020, as disclosed in notes 2.3 and 26, on the Group's financial position and management's going concern assessment;
- We challenged management's assessment the effects of the Covid 19 outbreak on the Group's ability to continue as a going concern.

### ***Responsibilities of the administrative body for the drafting of the consolidated financial statements***

The administrative body is responsible for the preparation of consolidated financial statements that give a true and fair view in accordance with the International Financial Reporting Standards (IFRS) as adopted by the European Union and with the legal and regulatory provisions applicable in Belgium, and for such internal control as the administrative body determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatements, whether due to fraud or error.

In preparing the consolidated financial statements, the administrative body is responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the administrative body either intends to liquidate the Group or to cease operations, or has no realistic alternative but to do so.

### ***Statutory auditor's responsibilities for the audit of the consolidated financial statements***

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue a statutory auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but it is not a guarantee that an audit conducted in accordance with ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

When executing our audit, we respect the legal, regulatory and normative framework applicable for the audit of the consolidated financial statements in Belgium. However, a statutory audit does not guarantee the future viability of the Group, neither the efficiency and effectiveness of the management of the Group by the administrative body.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control;

- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control;  
Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the administrative body;
- Conclude on the appropriateness of the administrative body's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our statutory auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our statutory auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern;
- Evaluate the overall presentation, structure and content of the consolidated financial statements and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation;
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the management, the supervision and the performance of the Group audit. We assume full responsibility for the auditor's opinion.

We communicate with the Audit Committee regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control identified during the audit.

We also provide the Audit Committee with a statement that we respected the relevant ethical requirements relating to independence, and we communicate with them about all relationships and other issues which may influence our independence, and, if applicable, about the related measures to guarantee our independence.

From the matters communicated with the Audit Committee, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current year, and are therefore the key audit matters. We describe these matters in our statutory auditor's report, unless law or regulation precludes public disclosure about the matter.

## OTHER LEGAL AND REGULATORY REQUIREMENTS

### *Responsibilities of the administrative body*

The administrative body is responsible for the preparation and the contents of the management report on the consolidated financial statements and for the other information included in the annual report on the consolidated financial statements.

### *Responsibilities of the statutory auditor*

In the context of our mandate and in accordance with the Belgian standard (version revised in 2020) which is complementary to the International Standards on Auditing (ISA) as applicable in Belgium, it is our responsibility to verify,



in all material aspects, the management report on the consolidated financial statements and the other information included in the management report on the consolidated financial statements, as well as to report on these elements.

### ***Aspects relating to the management report on the consolidated financial statements and to the other information included in the annual report on the consolidated financial statements***

In our opinion, after having performed specific procedures in relation to the management report, this report is consistent with the consolidated financial statements for the same financial year, and it is prepared in accordance with article 3:32 of the Code of companies and associations.

In the context of our audit of the consolidated financial statements, we are also responsible for considering, in particular based on the knowledge we have obtained during the audit, whether the management report on the consolidated financial statements and the other information included in the annual report on the consolidated financial statements, namely:

- Part I: Strategy & Business Review;
- Part II: Corporate Governance;
- Part III: Principle Risks & Uncertainties.

contain a material misstatement, i.e. information which is inadequately disclosed or otherwise misleading. Based on the procedures we have performed, there are no material misstatements we have to report to you.

### ***Statement concerning independence***

Our audit firm and our network did not provide services which are incompatible with the statutory audit of the consolidated financial statements and our audit firm remained independent of the Group during the terms of our mandate.

### ***Other statements***

This report is in compliance with the contents of our additional report to the Audit Committee as referred to in article 11 of regulation (EU) No 537/2014.

Zaventem, 28 April 2020

**BDO Réviseurs d'Entreprises SCRL**

*Statutory auditor*

Represented by Gert Claes

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# Condensed non-consolidated financial statements

The statutory financial statements to be filed with the Belgian National Bank are prepared in accordance with Belgian GAAP. An unqualified audit opinion will be issued by the statutory auditor.

The information included in this section is an extract from the statutory accounts and does not include all information as required by articles 98 and 100 of the Company laws. The full statutory accounts have not yet been filed with the Belgian National Bank as of the date of this document. Once filed with the Belgian National Bank, the full statutory accounts will also be made available in the investor section of MDxHealth's website ([www.mdxhealth.com](http://www.mdxhealth.com)).

## Statutory Income Statement

Thousands of €/For the years ended December 31	2019	2019 in \$ equivalent	2018
<b>I. Operating income</b>	<b>2,543</b>	<b>2,847</b>	<b>5,744</b>
A. Turnover	2,528	2,830	5,645
D. Other operating income	15	17	99
<b>II. Operating charges</b>	<b>5,945</b>	<b>6,656</b>	<b>7,160</b>
A. Purchase of goods and materials	47	53	390
B. Services and other goods	4,598	5,147	5,586
C. Remuneration, social security costs, pensions	1,273	1,425	1,151
D. Depreciation & amounts written off fixed assets	22	25	33
G. Other operating charges	5	6	-
<b>III. Operating profit/(loss)</b>	<b>(3,402)</b>	<b>(3,809)</b>	<b>(1,416)</b>
<b>IV. Financial income</b>	<b>2,681</b>	<b>3,002</b>	<b>2,233</b>
B. Income from current assets	2,624	2,938	2,081
C. Other	57	64	152
<b>V. Financial charges</b>	<b>110,726</b>	<b>123,957</b>	<b>311</b>
A. Debt charges	300	336	50
C. Non-recurring financial charges	110,426	123,621	261
<b>VI. Current profit/(loss) before taxes</b>	<b>(111,447)</b>	<b>(124,764)</b>	<b>506</b>
<b>IX. Profit/(loss) before taxes</b>	<b>(111,447)</b>	<b>(124,764)</b>	<b>506</b>
<b>X. Income taxes</b>			
<b>XI. Profit/(loss) for the year after taxes</b>	<b>(111,447)</b>	<b>(124,764)</b>	<b>506</b>

## Appropriation account

Thousands of €/For the years ended December 31	2019	2019 in \$ equivalent	2018
A. Loss/gain to be appropriated			
A1. Loss/Gain for the period available for appropriation	(111,447)	(124,764)	506
A2. Loss brought forward	(6,971)	(8,270)	(7,477)
B. Transfer from capital and reserves			
B1. From capital and share premium account			
C. Transfer to equity			
D. Result to be carried forward			
D2. Loss to be carried forward	118,418	133,034	6,971

## Statutory Balance Sheet

### Statutory Balance Sheet after appropriations

Thousands of €/For the years ended December 31	2019	2019 in \$ equivalent	2018
<b>ASSETS</b>	<b>48,129</b>	<b>54,067</b>	<b>138,489</b>
<b>I. Formation expenses</b>	-	-	-
<b>II. Intangible assets</b>			
<b>III. Tangible fixed assets</b>	<b>44</b>	<b>49</b>	<b>63</b>
B. Plant, machinery and equipment	44	49	63
C. Furniture and vehicles	-	-	-
<b>IV. Financial assets</b>	<b>48,085</b>	<b>54,018</b>	<b>138,426</b>
A. Affiliated enterprises	48,069	54,000	138,410
A1. Investments	3,422	3,844	9,171
A2. Amounts receivable	44,647	50,156	129,239
C. Other financial assets	-	-	-
C1. Investments	-	-	-
C2. Amounts received and cash guarantee	16	18	16
<b>CURRENT ASSETS</b>	<b>16,494</b>	<b>18,529</b>	<b>22,488</b>
<b>V. Amounts receivable after one year</b>	-	-	-
<b>VI. Stocks and contracts in progress</b>	-	-	-
<b>VII. Amounts receivable within one year</b>	<b>155</b>	<b>174</b>	<b>282</b>
A. Trade debtors	109	122	180
B. Other amounts receivable	46	52	102
<b>VIII. Investments</b>	<b>16,273</b>	<b>18,281</b>	<b>22,148</b>
B. Other investments and deposits	-	-	-
<b>IX. Cash at bank and in hand</b>	<b>16,273</b>	<b>18,281</b>	<b>22,148</b>
<b>X. Deferred charges and accrued income</b>	<b>66</b>	<b>74</b>	<b>58</b>
<b>TOTAL ASSETS</b>	<b>64,623</b>	<b>72,596</b>	<b>160,977</b>

## Statutory Balance Sheet after appropriations

Thousands of € For the years ended December 31	2019	2019 in \$ equivalent	2018
<b>CAPITAL AND RESERVES</b>	<b>49,920</b>	<b>56,076</b>	<b>152,366</b>
<b>I. Capital</b>	<b>56,260</b>	<b>63,202</b>	<b>47,813</b>
A. Issued capital	56,260	63,202	47,813
<b>II. Share premium account</b>	<b>112,078</b>	<b>125,908</b>	<b>111,524</b>
<b>III. Revaluation surpluses</b>	-	-	-
<b>IV. Reserves</b>	-	-	-
<b>V. Accumulated profit/(loss)</b>	<b>(118,418)</b>	<b>(133,034)</b>	<b>(6,971)</b>
<b>VI. Investment grants</b>	-	-	-
<b>VII. Provisions and postponed taxes</b>	-	-	-
A. Provisions for liabilities and charges	-	-	-
A4. Other liabilities & charges	-	-	-
<b>AMOUNTS PAYABLE</b>	<b>15,588</b>	<b>16,520</b>	<b>8,611</b>
<b>VIII. Debts payable after 1 year</b>	<b>8,186</b>	<b>9,196</b>	<b>31</b>
A. Financial debts	8,186	9,196	31
A4. Credit institutions	22	25	31
A5. Other debts	8,164	9,171	-
<b>IX. Debts payable within 1 year</b>	<b>2,205</b>	<b>2,477</b>	<b>1,844</b>
A. Current portion of debts after one year	-	-	-
B. Financial debts	516	580	136
B1. Credit institutions	516	580	136
C. Trade debts	1,605	1,803	1,451
C1. Suppliers	1,605	1,803	1,451
D. Advances received on contracts in progress	-	-	-
E. Taxes, remuneration & social security	84	94	257
E1. Taxes	1	1	-
E2. Remuneration & social security	83	93	257
<b>X. Accrued charges and deferred income</b>	<b>4,312</b>	<b>4,847</b>	<b>6,736</b>
<b>TOTAL LIABILITIES</b>	<b>64,623</b>	<b>72,596</b>	<b>160,977</b>





# Part V: Additional information

## Shareholder information

### Capital and shares

The descriptions provided below are only a summary and do not purport to give a complete overview of the Company's articles of association nor all relevant provisions of Belgian law. Neither should it be viewed as legal advice regarding the shares.

### History of share capital

At the end of 2019, the issued capital of MDxHealth amounted to € 56,250,102.01 represented by 70,528,525 common shares without nominal value.

The table below provides an overview of the history of the Company's share capital since its incorporation in 2003. The overview should be read together with the notes set out below the table.

Date	Transaction	Number of shares issued	Issue price per share (EUR)	Issue price per share post stock-split (EUR)	Capital increase (EUR)	Share capital after transaction (EUR)	Share Issuance Premium after transaction (EUR)	Aggregate # of shares after capital increase
<b>Incorporation</b>								
Jan. 10, 2003	Incorporation	202,975	0.30	0.06	61,500.00	61,500.00	0	202,975
<b>Phase I Financing Round December 20, 2002 (Preferred A Shares)</b>								
Feb. 7, 2003	Capital increase in cash	197,025	20.00	4.00	3,940,500.00	4,002,000.00	0	400,000
Jun. 30, 2003	Capital increase in cash	33,333	20.00	4.00	666,660.00	4,668,660.00	0	433,333
Sep. 30, 2003	Capital increase in cash	218,139	22.31	4.46	4,866,681.09	9,535,341.09	0	651,472
Jun. 20, 2004	Capital increase in cash	195,504	23.87	4.77	4,666,680.48	14,202,021.57	0	846,976
<b>Phase II Financing Round October 19, 2005 (Preferred B Shares)</b>								
Oct. 28, 2005	Capital increase in cash	375,000	24.00 <sup>(7)</sup>	4.80 <sup>(7)</sup>	9,000,000.00	23,202,021.57	0	1,221,976
Mar. 31, 2006	Capital increase in cash	193,548	31.00	6.20	5,999,988.00	29,202,009.57	0	1,415,524



Stock Split								
May 23, 2006	Stock split 5/1	/	/	/	/	/	0	7,077,620
Initial Public Offering and Exercise of Over-Allotment Warrants								
Jun. 30, 2006	Capital increase in cash	2,933,334	7.50	7.50	22,000,005.00	51,202,014.57	0	10,010,954
Jun. 30, 2006	Capital decrease	/	/	/	-10,217,809.00	40,984,205.57	0	10,010,954
Jun. 30, 2006	Capital increase through exercise of warrants	440,000	7.50	7.50	1,817,200.00	42,801,405.57	1,482,800.00	10,450,954
Exercise of Warrants								
Apr. 18, 2007	Capital increase through exercise of warrants	182,560	4.70	4.70	747,666.16	43,549,071.73	1,593,731.31	10,633,514
Private Placement								
Oct. 19, 2007	Capital increase in cash	1,063,351	10.00	10.00	4,354,954.02	47,904,025.75	7,872,287.29	11,696,865
Exercise of Warrants								
Oct. 25, 2007	Capital increase through exercise of warrants	50,837	4.73	4.73	208,202.93	48,112,228.68	7,904,487.77	11,747,702
Exercise of Warrants								
Apr. 24, 2008	Capital increase through exercise of warrants	61,120	4.59	4.59	250,316.96	48,362,545.64	7,934,871.81	11,808,822
Nov. 5, 2008	Capital increase through exercise of warrants	19,375	4.73	4.73	79,350.31	48,441,895.95	7,947,140.25	11,828,197
Private Placement								
Dec. 18, 2008	Capital increase in cash	1,332,877	6.29	6.29	5,458,797.75	53,900,693.70	10,872,138.83	13,161,074
Exercise of Warrants								
Apr. 17, 2009	Capital increase through exercise of warrants	24,540	4.49	4.49	100,503.57	54,001,197.27	10,881,808.74	13,185,614
Reduction of Share Capital								
Jun. 21, 2010	Share Capital reduction	/	/	/	/	10,517,661.90	10,881,808.74	13,185,614
Private Placement								
Apr. 8, 2011	Capital increase in cash	5,436,713	1.50	1.50	4,336,865.96	14,854,527.86	14,700,012.24	18,622,327
Private Placement								
Jul. 4, 2012	Capital increase in cash	6,891,113	1.45	1.45	5,497,040.84	20,351,568.70	19,202,971.61	25,513,440
Private Placement								
Jun. 25, 2013	Capital increase in cash	8,737,863	2.05	2.05	6,970,193.32	27,321,762.02	30,232,776.07	34,251,303
Private Placement								
Nov. 7, 2014	Capital increase in cash	3,425,000	3.60	3.60	2,732,122.50	30,053,884.52	39,830,653.57	37,676,303
Exercise of Warrants								
Apr. 30, 2015	Capital increase through exercise of warrants	172,187	2.01	2.01	137,353.57	30,191,238.09	40,039,189.53	37,848,490

<b>Private Placement</b>								
Jun. 26, 2015	Capital increase in cash	6,150,000	4.50	4.50	4,905,855.00	35,097,093.09	62,808,334.53	43,998,490
<b>Private Placement</b>								
Sep. 18, 2015	Capital increase in cash	1,086,956	4.14	4.14	867,064.80	35,964,157.89	66,441,267.57	45,085,446
<b>Exercise of Warrants</b>								
Nov. 27, 2015	Capital increase through exercise of warrants	68,187	1.70	1.70	54,392.77	36,018,550.66	66,502,756.44	45,153,633
<b>Exercise of Warrants</b>								
May 9, 2016	Capital increase through exercise of warrants	116,000	1.70	1.70	92,533.20	36,111,083.86	66,607,143.24	45,269,633
<b>Private Placement</b>								
Nov. 7, 2016	Capital increase in cash	4,526,962	4.50	4.50	3,611,157.59	39,722,241.45	83,367,314.65	49,796,595
<b>Exercise of Warrants</b>								
Nov. 10, 2016	Capital increase through exercise of warrants	49,000	1.69	1.69	39,087.30	39,761,328.75	83,410,887.35	49,845,595
<b>Exercise of Warrants</b>								
May 5, 2017	Capital increase through exercise of warrants	103,813	1.94	1.94	82,811.63	39,844,140.38	83,529,614.08	49,949,408
<b>Private Placement</b>								
Mar. 26, 2018	Capital increase in cash	9,989,881	3.60	3.60	7,968,928.07	47,813,068.45	111,524,257.61	59,939,289
<b>Private Placement</b>								
Oct. 1, 2019	Capital increase in cash	10,589,236	0.85	0.85	8,447,033.56	56,260,102.01	112,078,074.65	70,528,525
<b>Per statutory accounts</b>						56,260,102.01	112,078,074.65	70,528,525
<b>Per IFRS consolidated accounts</b>						49,754,340.36	112,078,074.65	70,528,525

## Authorized capital

By virtue of the resolution of the extraordinary general shareholders' meeting held on June 20, 2016, the Board of directors was expressly authorized to increase the share capital in one or more transactions by a total value of thirty-six million, one hundred and eleven thousand, eighty-three euros and eighty-six cents (€36,111,083.86) (the "Authorized Capital Amount").

The Board of Directors may exercise this power for a period starting on the date of the publication of the relevant resolution of the extraordinary general shareholders' meeting in the Annexes to the Belgian Official Gazette and ending on the date of the annual general shareholders' meeting to be held in 2021 which shall resolve on the annual accounts relating to the financial year ending on December 31, 2020.

This authorization may be renewed in accordance with the relevant legal provisions.

The capital increases to which can be decided according to this authorization, can take place in accordance with the modalities as are to be decided by the Board of Directors, such as:

- by means of contribution in cash or in kind, within the limits as permitted by the Belgian Company Code,
- through conversion of reserves and issuance premiums,
- with or without issuance of new shares, with or without voting rights,
- through issuance of convertible bonds, subordinated or not,
- through issuance of warrants or bonds to which warrants or other tangible values are attached, and/or
- through issuance of other securities, such as shares in the framework of a stock option plan.

In the framework of the use of its powers within the framework of the Authorized Capital, the Board of Directors can limit or cancel the preferential subscription right of the shareholders in the interest of the Company, subject to the limitations and in accordance with the conditions provided for by the Belgian Company Code. This limitation or cancellation can also occur to the benefit of the employees of the Company and its subsidiaries, and, to the extent permitted by law, to the benefit of one or more specific persons that are not employees of the Company or its subsidiaries.

If, following a capital increase that has been decided within the framework of the Authorized Capital, an issuance premium is paid, the Board of Directors is authorized and obliged to book the amount of such issuance premium onto the account "Issuance Premiums", that shall serve as guarantee for third parties in the same manner as the Company's share capital and which, apart from the possibility to convert this reserve into share capital, can only be disposed of in accordance with the rules provided by the Belgian Company Code for amendments to the articles of association.

By virtue of the resolution of the extraordinary general shareholders' meeting held on June 20, 2016, the Board of directors was also expressly authorized to increase the share capital in one or more transactions following a notification by the Belgian Financial Services and Markets Authority that it has been informed of a public takeover bid for the company's financial instruments, through contributions in cash with cancellation or limitation of the preferential subscription rights of the shareholders (including for the benefit of one or more well defined persons who are not employees of the company) or through contributions in kind, with issuance of shares, warrants or convertible bonds, subject to the terms and conditions provided for in the Belgian Companies Code. The Board of directors may exercise this power for a period of up to three years starting as of the date of the publication of the relevant resolution of the extraordinary general shareholders' meeting in the Annexes to the Belgian Official Gazette.

The Board of Directors is authorized, with power of substitution, to amend the articles of association upon each capital increase realized within the framework of the Authorized Capital, to bring them in accordance with the new situation of the share capital and the shares. At the date of this document, the Board of Directors has used the above described powers under the Authorized Capital as follows:

- The board of directors has used its powers under the authorised capital provided for in article 6.1. on November 7, 2016 by issuing 4.526.962 new shares for a total of three million six hundred, eleven thousand, one hundred fifty-seven euro and fifty-nine cents (€ 3,611,157.59),
- on March 26, 2018, the board of directors has used its powers under the authorised capital provided for in article 6.1. by issuing 9.989.881 shares for a total of seven million, nine hundred sixty-eight thousand, nine hundred twenty-eight euro and seven cents (€7,968,928.07).
- on October 1, 2019, the board of directors has used its powers under the authorised capital provided for in article 6.1. by issuing 10,589,236 shares for a total of eight million, four hundred forty-seven thousand, thirty-three euro and fifty-six cents (€8,447,033.56).

As a result, the available amount for a share capital increase under the authorized capital is equal to sixteen million, eighty-three thousand, nine hundred sixty-four euro and sixty-four cents (€ 16,083,964.64).

## Rights attached to shares

### *Dividend Rights*

All shares entitle the holder thereof to an equal right to participate in the Company's profits (if any). Pursuant to the Belgian Company Code, the shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the annual general shareholders' meeting, based on the most recent statutory audited financial statements, prepared in accordance with the generally accepted accounting principles in Belgium and based on a (non-binding) proposal of the Company's Board of Directors. The Company's articles of association also authorize the Board of Directors to declare interim dividends on profits of the current financial year subject to the terms and conditions of the Belgian Company Code.

The Company's ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law based on the Company's statutory unconsolidated financial statements rather than its consolidated financial statements. In particular, dividends can only be distributed if following the declaration and issuance of the dividends the amount of the Company's net assets on the date of the closing of the last financial year as follows from the statutory non-consolidated financial statements (i.e., summarized, the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities, all in accordance with Belgian accounting rules), decreased with the non-amortized costs of incorporation and extension and the non-amortized costs for research and development, does not fall below the amount of the paid-up capital (or, if higher, the issued capital), increased with the amount of non-distributable reserves. In addition, prior to distributing dividends, 5% of the net profits must be allotted to a legal reserve, until the legal reserve amounts to 10% of the share capital.

The right to payment of dividends on registered and dematerialized shares expires five years after the Board of Directors declared the dividend payable.

The Company has never declared or paid any dividends on its shares and does not anticipate paying any dividends in the foreseeable future. At December 31, 2018, there were no profits available for distribution under Belgian law.

### *Preferential Subscription Rights*

In the event of a capital increase in cash with issue of new shares, or in the event of an issue of convertible bonds or warrants, the existing shareholders have a preferential right to subscribe, pro rata, to the new shares, convertible bonds or warrants. The general shareholders' meeting may decide to limit or cancel this preferential subscription right, subject to special reporting requirements. Such decision by the shareholder's meeting needs to satisfy the same quorum and majority requirements as the decision to increase the Company's share capital. The shareholders may also decide to authorize the Board of Directors to limit or cancel the preferential subscription right within the framework of the authorized capital, subject to the terms and conditions set forth in the Belgian Company Code.

### *Voting Rights*

Each shareholder of the Company is entitled to one vote per share. There are no different categories of shares. All shareholders have the same voting rights. Voting rights may be mainly suspended in relation to shares:

- which were not fully paid up, notwithstanding the request thereto of the Board of Directors of the Company;
- to which more than one person is entitled, except in the event a single representative is appointed for the exercise of the voting right;
- which entitle their holder to voting rights above the threshold of 3%, 5%, 7.5%, 10%, 15%, 20% and any further multiple of 5% of the total number of voting rights attached to the outstanding financial instruments of the Company on the date of the relevant general shareholders' meeting, in the event that the relevant shareholder has not notified the Company and the FSMA at least 20 days prior to the date of the general shareholders' meeting in accordance with the applicable rules on disclosure of major shareholdings; and
- of which the voting right was suspended by a competent court or the FSMA.

### *Rights to Participate and Vote at Shareholder's Meetings*

## **Annual general shareholders' meeting**

The annual general shareholders' meeting is held at the registered office of the Company or at the place determined in the notice convening the shareholders' meeting. The meeting is held every year on the last Thursday of May at 10 a.m. If this day would be a Belgian public holiday, the annual general shareholders' meeting shall be held on the previous Business Day. In these articles of association, "Business Day" shall mean any calendar day, with the exception of Saturdays, Sundays and Belgian public holidays.

At the annual general shareholders' meeting, the Board of Directors submits the audited statutory and consolidated financial statements and the reports of the Board of Directors and of the statutory auditor with respect thereto to the shareholders. The shareholders' meeting subsequently decides on the approval of the statutory financial statements, the proposed allocation of the Company's profit or loss, the discharge from liability of the Directors and the statutory auditor, and, when applicable, the (re)appointment or resignation of the statutory auditor and/or of all or certain Directors and their remuneration. In addition, as relevant, the annual general shareholders' meeting must also decide on the approval of provisions of service agreements to be entered into with Executive Directors, members of the management committee and other executives providing (as the case may be) for severance payments exceeding 12 months' remuneration (or, subject to a motivated opinion by the remuneration committee, 18 months' remuneration). As from the annual meeting held in 2012, the shareholders' meeting must also decide separately on the approval of the remuneration report included in the annual report.

## **Special and extraordinary general shareholders' meetings**

The Board of Directors or the statutory auditor may, whenever the interest of the Company so requires, convene a special or extraordinary general shareholders' meeting. Such shareholders' meeting must also be convened every time one or more shareholders holding at least 20% of the Company's share capital so demand. Shareholders that do not hold at least 20% of the Company's share capital do not have the right to convene such special or extraordinary general shareholders' meeting.

## **Notices convening the general meeting**

The notice convening the general shareholders' meeting must indicate : (i) the agenda, place, date, and time of the meeting; (ii) the items to be discussed and the proposed resolutions that will be submitted to the meeting; (ii) a clear

description of the formalities to be fulfilled by the shareholders in order to be entitled to participate to the general meeting and to exercise their voting right, including the period within which the shareholders should indicate to the Company their intention to participate to the meeting; (iv) a description of the procedure to vote by proxy (or at distance to the extent permitted by the articles of association); (v) details with regard to the right of shareholders to amend items of the agenda, require additional items/proposed resolutions to be put on the agenda, and ask questions; (vi) the timeframe within which such rights may be exercised and an electronic address to which shareholders may send their queries; (vii) the registration date and explanations related thereto; and (viii) the place as well as the website on which all relevant documents can be obtained. The meeting cannot deliberate and vote on items that are not mentioned on the agenda, unless all shareholders are present or represented and decide unanimously to place such items on the agenda.

The notice convening the shareholders' meeting must be published (i) in the annexes to the Belgian Official Gazette, (ii) a newspaper with nationwide distribution in Belgium, (iii) via media as may reasonably be relied upon for the effective dissemination of information to the public throughout the European Economic Area and (iv) the website of the Company at least 30 calendar days prior to the general meeting (or, if a second meeting is required, if the date of the second meeting was mentioned in the notice convening the first meeting and if the agenda has not changed, at least 17 days prior to the second meeting).

A publication in the Annexes to the Belgian Official Gazette and on the website of MDxHealth suffices for notices convening the annual general shareholders' meeting if such meeting takes place in Liège and on the place, date and hour referred to above and if the agenda is limited to the submission of the financial statements, the reports of the Board of Directors and statutory auditor relating thereto, the discharge from liability of the Directors and statutory auditor, the approval of provisions of service agreements and the approval of the remuneration report.

The holders of registered shares, warrants and bonds are personally notified by letter at least 30 days prior to the meeting.

Formalities to attend the general meeting:

All holders of shares, warrants or bonds (if any) issued by the Company can attend shareholders' meetings. Only shareholders, however, can vote at shareholders' meetings. To attend the general shareholders' meeting, holders of securities issued by the Company should consider the formalities and procedures described below.

## Registration for the meeting

Firstly, the right for a holder of securities to participate to and, as applicable, to vote at a general meeting is only granted on the basis of the registration of the securities concerned, fourteen days prior to the general meeting (the "registration date") at midnight, via registration, in the applicable register book for the securities concerned (for registered securities) or in the accounts of a certified account holder or relevant settlement institution for the securities concerned. Secondly, to be admitted to the general shareholders' meeting, the holders of securities issued by the Company must notify the Company or a centralizing bank designated in the convening notice whether they want to participate to the meeting. The notice must reach the Company by mail at its registered office or by e-mail at the latest on the sixth calendar day prior to the general shareholders' meeting. For the holders of dematerialized securities or securities in book-entry form, the notification should also include a certificate confirming the number of securities that have been registered in their name on the registration date. The certificate can be obtained by the holder of the dematerialized securities with his or her financial intermediary, the certified account holder or the applicable settlement institution for the securities concerned.

The registration procedure set forth here above is also applicable in the event where a second meeting needs to be convened, the required quorum not being present or represented at the first meeting.

## Power of attorney

Each holder of securities has the right to attend a general shareholders' meeting and to vote at the general shareholders' meeting in person or through a proxy holder, in conformity with applicable law. The proxy holder does not need to be a shareholder. The Board of Directors can request the participants to the meeting to use a model of power of attorney (with voting instructions). Such proxies must be in writing or via an electronic form, and must bear the shareholder's signature (which may be a digital signature as defined in article 1322, paragraph 2 of the Belgian Civil Code or as otherwise permitted by applicable law). In accordance with applicable law, the dated and signed proxy must be sent by letter, fax, email or any other means specified in article 2281 of the Belgian Civil Code to the Company's registered office or the place indicated in the notice and must reach the Company at the latest on the sixth calendar day prior to the general shareholders' meeting concerned. The holders of a proxy must comply with the provisions of the Belgian Company Code regarding proxies for general shareholders' meetings.

Holders of securities who wish to be represented by proxy must, in any case, comply with the formalities to register for the meeting, as explained under "Registration for the meeting" above.

## Amendments to the agenda and additional proposed resolutions

Shareholders who alone or together with other shareholders hold at least 3% of the outstanding shares of the Company have the right to put additional items on the agenda of the annual and extraordinary general shareholders' meetings and to table draft resolutions in relation to items that have been or are to be included in the agenda. If the required quorum for the extraordinary general shareholders' meeting is not reached and a second extraordinary general shareholders' meeting is convened, this right will not apply in relation to the agenda of the second extraordinary general shareholders' meeting. Shareholders wishing to exercise this right must prove on the date of their request, that they own at least 3% of the outstanding shares. The ownership must be based, for dematerialized shares, on a certificate issued by the applicable settlement institution for the securities concerned, or by a certified account holder, confirming the number of securities that have been registered in the name of relevant shareholders and, for registered shares, on a certificate of registration of the relevant shares in the share register book of the Company. In addition, the shareholder concerned must, in any case, comply with the formalities to register for the meeting (as explained under "—Registration for the meeting" above) with at least 3% of the outstanding shares. A request to put additional items on the agenda and/or to table draft resolutions must be submitted in writing, and must contain in the event of an additional agenda item, the text of the agenda item concerned and, in the event of a draft resolution, the text of the draft resolution. The request must also mention the mail or e-mail address to which the Company will send the confirmation of receipt of the request. The request must reach the Company by mail at its registered office or by e-mail at the e-mail address mentioned in the notice convening to the general meeting at the latest on the twenty second calendar day prior to the annual and extraordinary general shareholders' meeting. In case of amendments to the agenda and proposed additional resolutions as aforementioned, the Company will publish an amended agenda with, as the case may be, additional agenda items and additional draft resolutions no later than on the fifteenth calendar day prior to the annual and/or extraordinary general shareholders' meeting. In addition, the Company shall make amended forms available for votes by mail and votes by proxy. Proxies and votes by mail that reach the Company prior to the publication of an amended agenda remain valid for the agenda items to which the proxies and votes by mail apply, subject, however, to applicable law and the further clarifications set out on the proxy forms and postal voting form.



## Right to ask questions

Within the limits of article 540 of the Belgian Companies Code, shareholders have the right to ask questions to the Directors in connection with the report of the Board of Directors or the items on the agenda of such shareholders' meeting.

Shareholders can also ask questions to the statutory auditor in connection with its report. Such questions can be submitted in writing prior to the meeting or can be asked at the meeting. Written questions must be received by the Company by mail at its registered office or by e-mail no later than the sixth day prior to the meeting. Written and oral questions will be answered during the meeting concerned in accordance with applicable law. In addition, for written questions to be considered, the shareholders who submitted the written questions concerned must comply with the formalities to attend the meeting, as explained under "Registration for the meeting" above.

## Quorum and majorities

In general, there is no quorum requirement for a shareholders' meeting and decisions are generally passed with a simple majority of the votes of the shares present and represented. However, capital increases (other than those decided by the Board of Directors pursuant to the authorized capital), decisions with respect to the Company's dissolution, mergers, de-mergers and certain other reorganizations of the Company, amendments to the articles of association (other than an amendment of the corporate purpose), and certain other matters referred to in the Belgian Company Code do not only require the presence or representation of at least 50% of the share capital of the Company but also the approval of at least 75% of the votes cast. An amendment of the Company's corporate purpose, requires the approval of at least 80% of the votes cast at a shareholders' meeting, which can only validly pass such resolution if at least 50% of the share capital of the Company and at least 50% of the profit certificates, if any, are present or represented. In the event where the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second shareholders' meeting may validly deliberate and decide regardless of the number of shares present or represented. The special majority requirements, however, remain applicable.

## Disclosures within the framework of the takeover directive

### *Capital structure*

At the end of 2019, the issued capital of MDxHealth SA amounted to €56,260,102.01 represented by 70,528,525 fully paid-up common shares without nominal value. All shares have the same rights and obligations and participate equally in the profits of MDxHealth SA.

MDxHealth SA does not own any of the issued and outstanding shares of MDxHealth SA.

Shareholders holding more than 3% of the outstanding shares of the Company who make themselves known to the Company and to the FSMA are disclosed above in "Board Report; Corporate Governance Statement; Shareholding Structure" and on the Company's website at [www.mdxhealth.com/investors/shareholder-information](http://www.mdxhealth.com/investors/shareholder-information).

*Restrictions concerning the transfer of securities*

The Company's articles of association do not impose any restrictions on the transfer of securities in addition to the restrictions provided for in the Belgian Company Code.

*Holders of securities with special control rights*

The Company has not granted any special control rights to the holders of its securities.

*Mechanism for control of share plans for employees*

There are no shares or similar plans for employees other than the stock option plans disclosed elsewhere in this document.

*Restrictions concerning the exercise of the voting right*

Each shareholder of MDxHealth SA is entitled to one vote per share. There is only one category of shares (common shares). Voting rights can be suspended, amongst others, in relation to shares:

- which were not fully paid up, notwithstanding the request thereto of the Board of Directors of the Company;
- to which more than one person is entitled, except in the event a single representative is appointed for the exercise of the voting right;
- which entitle their holder to voting rights above the threshold of 3%, 5%, or any multiple of 5% of the total number of voting rights attached to the outstanding financial instruments of the Company on the date of the relevant general shareholders' meeting, except in the event where the relevant shareholder has notified the Company and the FSMA at least 20 days prior to the date of the general shareholders' meeting on which he or she wishes to vote of its shareholding exceeding the thresholds above; and
- of which the voting right was suspended by a competent court or the FSMA.

*Agreements between shareholders which are known to the Company and may result in restrictions on the transfer of securities and/or exercise of voting rights*

There are no declared or known agreements between shareholders.

*Significant agreements which take effect alter or terminate upon a change of control of the Company following a takeover bid*

According to the terms and conditions of the warrants issued by MDxHealth, non-vested warrants become exercisable in case of a change of control of the Company. In addition, material agreements with Exact Sciences include change of control clauses.

*Agreements with Directors or employees providing for compensation if they resign or are made redundant without valid reason or if their employment ceases because of a public takeover bid*

There are individual agreements between the Company and certain Members of the Management Committee that provide a severance payment of up to 18 months, should this agreement be terminated due to the Company's change of control.

After deliberation and decision upon the annual accounts, the shareholders' meeting shall be requested to release the Directors and the statutory auditor from liability for the execution of their mandate during the past fiscal year.

## Notification of Important Participations

The Belgian Company Code, applicable legislation and article 14 of the Company's articles of association provide that every natural person or legal entity acquiring or transferring shares or other financial instruments of a listed company that entitle the holder thereof to voting rights, whether or not representing the Company's share capital (such as warrants, stock options, or automatic convertible bonds, if any), must immediately and at the latest four Euronext business days following the transaction, notify the Company and the FSMA of the total number of financial instruments that he or she holds each time where, as a result of the acquisition or transfer, the total number of voting financial instruments exceeds or falls below a threshold of 3%, 5%, 10% or 15% (or every subsequent multiple of 5%) of the total number of financial instruments at the moment of the transaction.

All persons acting individually must make the notification. It must also be made by affiliated persons or persons acting in concert with respect to the holding, acquisition or transfer of voting financial instruments. In that event, the voting financial instruments of the affiliated persons or persons acting in concert must be combined for the purpose of determining whether a threshold is passed. The forms to make the aforementioned disclosures, as well as further explanations can be found on the website of the FSMA ([www.FSMA.be](http://www.FSMA.be)).

The FSMA and the commercial court can suspend voting rights attached to voting financial instruments that have not been disclosed in accordance with the foregoing provisions. In addition, the president of the commercial court can also order the sale of the financial instruments to a third party. In any event, shareholders cannot vote at shareholders' meetings with more voting rights than they have notified in accordance with the above rules at least 20 days prior to a shareholders' meeting.

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# Glossary

<b>Assay</b>	A term for a single experiment or a diagnostic test incorporating the required markers to analyze a clinical specimen.
<b>Biopsy</b>	A procedure where a tumor tissue sample is removed from the body for laboratory examination to determine whether cancer or some other disease is present. A biopsy can be performed using a needle to extract a small number of cells or as a surgical procedure to remove a larger piece of tissue.
<b>Biotechnology</b>	Biotechnology is a technology based on or influencing biological processes, especially when used in agriculture, food science, and medicine.
<b>Cancer</b>	Cancer is a type of disease caused by genetic instability and characterized by uncontrolled division of cells and the ability of these cells to invade other organs.
<b>CAP</b>	The College of American Pathologists (CAP) is a US accrediting agency for the US Centers for Medicare and Medicaid Services (CMS).
<b>Cell</b>	The basic unit of a living organism. Each cell is surrounded by a membrane and has a nucleus containing a set of genes that provide it with the information necessary to operate and divide.
<b>CLIA</b>	The US Clinical Laboratory Improvement Amendments (CLIA) establishes quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results.
<b>Clinical sample</b>	A sample taken from the body (ex. blood, urine, tissue) and analyzed to gain information about a person's medical state.
<b>Clinical trial</b>	A research study, usually in diseased patients, to test drugs, procedures, or testing technologies to determine how well they work compared to other practices or the natural course of the disease.
<b>CMS</b>	US Centers for Medicare & Medicaid Services
<b>CPT codes</b>	Current Procedural Terminology Codes- numbers assigned to every medical task used by physicians and or laboratories to determine amount of reimbursement that practitioner will receive from insurer. CPT codes are assigned by AMA American Medical Association to provide uniform definition for services and reimbursement.
<b>Diagnosis</b>	Identification of a condition or disease (ex. breast cancer), by its signs, symptoms, and the results of laboratory or histopathological tests.
<b>DNA (deoxyribonucleic acid)</b>	DNA is a nucleic acid polymer, usually in the form of a double helix, of which the genes are made and code for life processes.
<b>Epigenetics</b>	Refers to heritable changes in gene expression (active versus inactive genes) that does not involve changes to the underlying DNA sequence (i.e., a change in phenotype without a change in genotype). This in turn affects how cells read the genes. Epigenetic change is a regular and natural occurrence but can also be influenced by several factors including age, the environment/lifestyle, and disease state.
<b>Gene</b>	A unit of genetic information. Genes are encoded in a cell's DNA and the proteins they express control the physical development and behavior of the cell or the whole organism.
<b>In-Vitro Diagnostics (IVD)</b>	IVDs are tests performed outside the human body on clinical samples such as blood, urine, or biopsy tissue.
<b>Kit (diagnostic kit)</b>	In-vitro diagnostic test that is packaged in a box which that can be shipped to end-user laboratories.
<b>LDT</b>	Laboratory Developed Test-refer to assays developed in a laboratory for use within that laboratory. While these tests are not currently regulated by FDA Food and Drug Administration, the lab must validate all aspects of the test to ensure patient safety, reliability, repeatability, accuracy as well as validating all instruments, reagents and or supplies used in the test.

<b>Marker</b>	A substance native to the organism, whose presence is indicative of a specific medical condition.
<b>Medicaid</b>	Medicaid is a medical assistance program in the US established by Title XIX of the US Social Security Act. The Medicaid program is a no-cost or low-cost public health insurance program for US residents that provides needed health care services for low-income and disabled individuals.
<b>Medicare</b>	Medicare is a national social insurance program, administered by the U.S. federal government, established in 1966 under Title XVIII of the US Social Security Act. Medicare provides health insurance for US residents aged 65 and older who have worked and paid into the system. It also provides health insurance to younger people with certain disabilities and designated diseases.
<b>Methylation</b>	Control mechanism that regulates gene expression in DNA without causing a permanent genetic alteration.
<b>Methylation-Specific PCR (MSP)</b>	A technology for detecting gene methylation.
<b>MGMT</b>	The O6-methylguanine DNA-methyltransferase (MGMT) gene has been widely studied and shown to be able to predict glioblastoma cancer patient response to alkylating agents.
<b>NPV</b>	NPV or “Negative Predictive Value” is the probability that subjects with a negative test truly don’t have the disease being tested. It is a numerical value for the proportion of individuals with a negative test result who are free of the target condition.
<b>PCR</b>	The polymerase chain reaction is a technique for the in vitro amplification of specific DNA sequences by the simultaneous primer extension of complementary strands of DNA.
<b>Pharmacogenomics</b>	The study and application of DNA and RNA based biomarkers to predict how an individual's genes affect the body's response to a therapeutic drug.
<b>PSA</b>	Prostate-Specific-Antigen, a widely used but widely criticized blood-based screening test for prostate cancer.
<b>Recurrence</b>	A return of cancer after treatment.
<b>Screening</b>	The testing of a population for disease.
<b>Sensitivity</b>	A measure of a diagnostic test’s accuracy. Sensitivity measures the percentage of people with a certain medical condition that produces a positive test result. Tests with good sensitivity produce few false negative results.
<b>Service Laboratory</b>	Laboratory that provides medical testing services.
<b>Specificity</b>	A measure of a diagnostic test’s accuracy. Specificity measures what percentage of people without a medical condition for whom the test result is negative. Tests with good specificity produce few false positive results.
<b>Tumor</b>	Tissue growth where the cells that make up the tissue have multiplied uncontrollably. A tumor can be benign (non-cancerous) or malignant (cancerous).
<b>Validation (Product Pipeline Step)</b>	A phase within the product development process to evaluate the performance of the newly developed assay using a defined sample set.

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#### Colofon

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